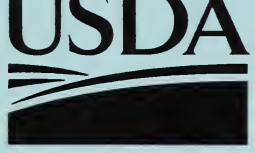
HACCP

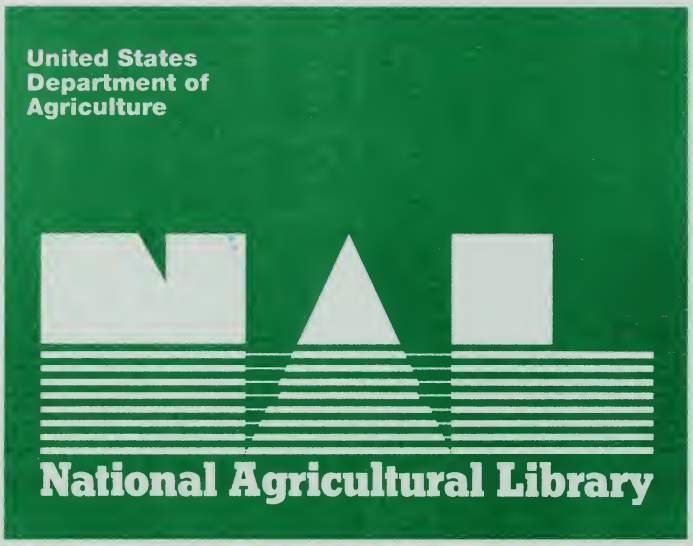
Regulatory Process For HACCP-Based Inspection Reference Guide January 1998



United States Department of Agriculture

Food Safety and Inspection Service • Human Resources Development Staff

FSIS-HACCP-1


United States
Department of
Agriculture
National Agricultural Library

HACCP

Regulatory Process For HACCP-Based Inspection

Reference Guide

January 1998

U.S. Department of Agriculture
Food Safety and Inspection Service

Field Operations

Room 4449 - South Building
Washington, DC 20250

(202)720-3697

Human Resource Development Staff

2700 E. Bypass, Suite 3000
Crystal Park Plaza
College Station, TX 77845

(409)260-9562

For sale by the U.S. Government Printing Office
Superintendent of Documents, Mail Stop: SSOP, Washington, DC 20402-9328
ISBN 0-16-042771-1

HACCP Seven Principles

Principle 1 ***Conduct a Hazard Analysis***

Principle 2 ***Identify Critical Control Points***

Principle 3 ***Establish Critical Limits for Each Critical Control Point***

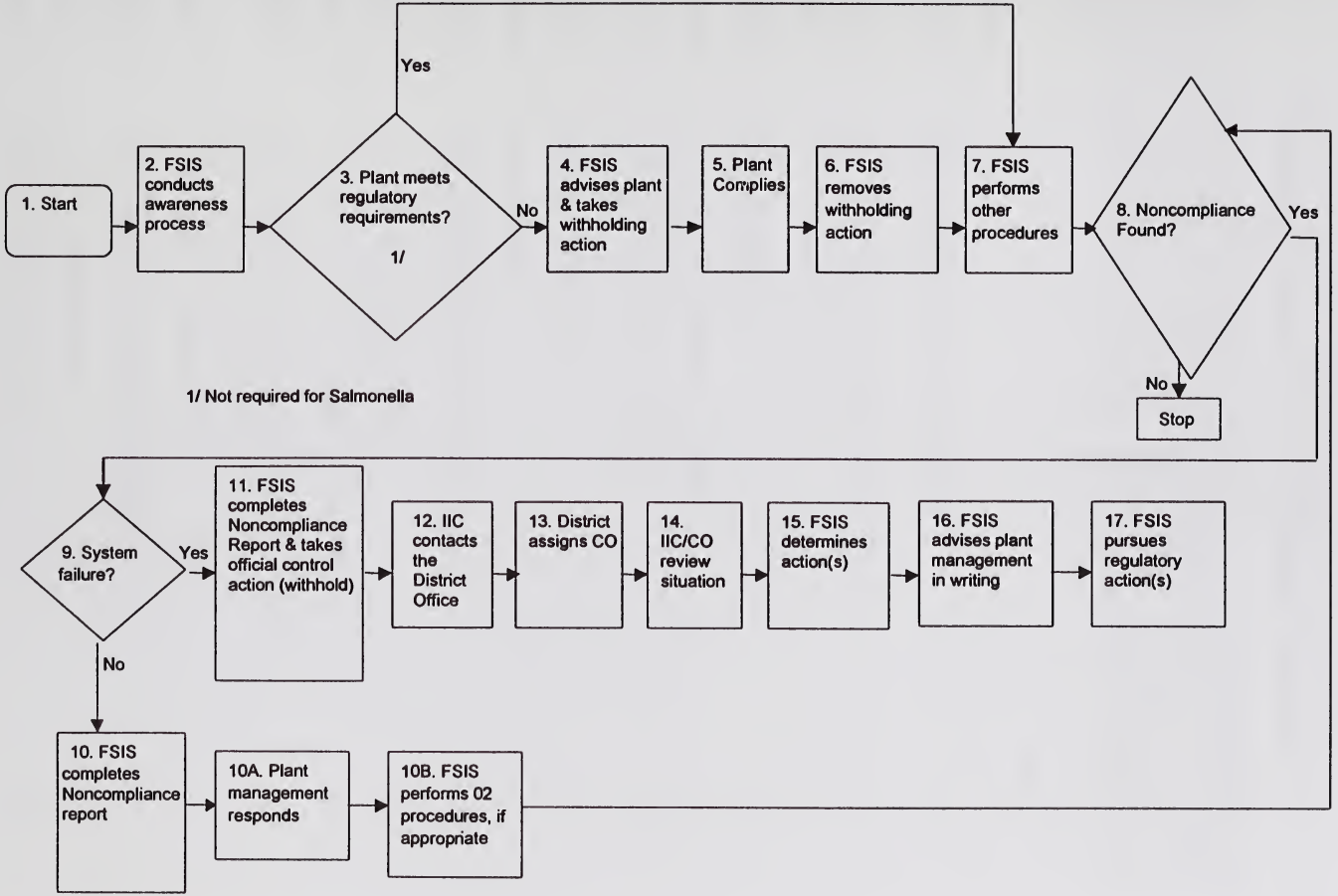
Principle 4 ***Establish Monitoring Procedures***

Principle 5 ***Establish Corrective Actions***

Principle 6 ***Establish Recordkeeping Procedures***

Principle 7 ***Establish Verification Procedures***

Regulatory Process For HACCP- Based Inspection



Contents

Regulatory Process For HACCP-Based Inspection

Note: The "blocks" listed below and illustrated in the flow diagram on the preceding page represent steps in the regulatory process. Each "block" discussion addresses the decisions and actions required by the FSIS inspector at that step of the process. When applicable, sections from the Pathogen Reduction/HACCP final rule and other regulatory references are noted.

Contents

Block 1—Start

Preamble to Pathogen Reduction/HACCP Final Rule

This final rule published in the July 25, 1996 *Federal Register* requires that federally inspected establishments implement HACCP systems to address hazards that are reasonably likely to occur in their operations. The HACCP systems mandated by this final rule focus on attributes affecting product safety, not those affecting economic adulteration or quality. On the effective dates of this final rule, FSIS will begin verifying HACCP system operations as part of its inspection program.

The HACCP regulations set forth in Title 9 of the Code of Federal Regulations (CFR) part 417 and related provisions set forth in 9 CFR parts 304, 327, and 381 will be applicable as follows:

1. In large establishments, defined as all establishments with 500 or more employees, on January 26, 1998.

2. In smaller establishments, defined as all establishments with 10 or more employees but fewer than 500, on January 25, 1999.

3. In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million, on January 25, 2000.

Inspection Under HACCP

HACCP-oriented food safety inspection changes the approach of FSIS to overseeing the safety of meat and poultry products. Under this new approach, FSIS will rely less on after-the-fact detection of product and process defects and more on verifying the effectiveness of processes and process controls designed to ensure food safety. FSIS will restructure its inspection procedures to determine that production systems prevent the production of unsafe meat and poultry products. FSIS will carry out various activities to ensure that industry HACCP systems meet the requirements of this rule, and are functioning as designed.

The establishment must comply with all regulatory requirements. The establishment must develop written plans/procedures for HACCP, SSOP, and *E. coli* testing. Any time inspection personnel determine that regulatory requirements have not been met, the noncompliance will be documented and appropriate enforcement action will be taken. Upon initiation, inspection personnel verify that the plan or procedure is apparently responding to all regulatory requirements. If a required feature is not included in the plan or procedure, the nonconformance is documented and enforcement action is taken. Additional verification activities and noncompliance documentation are used to

Block 1—Start

determine whether there has been a system failure. Enforcement is the action taken by inspection personnel when a failure has occurred.

Actions

Block I

Preparation is essential for success. Before performing any task for regulatory enforcement of part 417 or other regulatory requirements, FSIS inspection program personnel must ensure that they:

1. know the regulatory requirements for HACCP

2. have the equipment, supplies, and references needed to perform and document their inspection findings

Decisions

Once prepared, FSIS inspection program personnel will proceed to:

Block 2	if the task is conducting awareness process of a HACCP plan
Block 7	if the task is to perform other procedures

Block 2—FSIS Conducts Awareness Process

Before performing basic compliance/noncompliance procedures, it is essential that inspection program and plant personnel understand the HACCP plan of the plant. To accomplish such understanding, the Inspector in Charge (IIC) should hold an awareness meeting between inspection program personnel and plant personnel.

First, the IIC will decide who will be involved in the meeting. Key management personnel responsible for development and maintenance of the company's HACCP plan and inspection program personnel performing HACCP inspection procedures should participate in this meeting.

Second, the IIC will determine how much time will be needed for the meeting. The amount of time will vary according to the plant size and complexity of the plans. One to four days may be needed for meetings in large plants. From four hours to one day may be all that is needed in small and very small plants.

The IIC might request an opportunity to review the HACCP plan before the awareness meeting to help decide how much time will be needed for the meeting. An outline can be made for the items to be discussed. As the SSOP plan, however, the HACCP plan is property of the establishment.

Because HACCP plans are plant-specific, inspection program personnel cannot effectively perform HACCP procedures until they understand the plan. The awareness meeting provides an opportunity for inspection program personnel to familiarize themselves with the plan. They can also learn about the plan in operation, such as where the HACCP records are kept, how to gain access to the computer, and where the CCPs are located.

Block 2

Upon completing the Awareness meeting, proceed to:

Block 3 Plant Meets Regulatory Requirements?

Block 3—Plant Meets Regulatory Requirements?

Regulations–Sec. 417.2 Hazard Analysis and HACCP Plan

(a) Hazard analysis

(1) Every official establishment shall conduct, or have conducted, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred or because there is a reasonable possibility that it will occur in the particular type of product being processed in the absence of those controls.

(2) A flow chart describing the steps of each process in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards may be expected from the following:

(i) Natural toxins

(ii) Microbiological contamination

(iii) Chemical contamination

(iv) Pesticides

(v) Drug residues

(vi) Zoonotic diseases

(vii) Decomposition

(viii) Parasites

(ix) Unapproved use of direct or indirect food or color additives

(x) Physical hazards

(b) The HACCP plan

(1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment

whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter—all species

(ii) Raw product—ground

(iii) Raw product—not ground

(iv) Thermally processed—commercially sterile

(v) Not heat-treated—shelf-stable

(vi) Heat-treated—shelf-stable

(vii) Fully cooked—not shelf-stable

(viii) Heat-treated but not fully cooked—not shelf-stable

(ix) Product with secondary inhibitors—not shelf-stable

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X of the Federal meat and poultry inspection regulations.

(c) Contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this section pertaining to the specific process or product, are met

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits

(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of the Federal meat and poultry inspection regulations, to be followed in response to any deviation from a critical limit at a critical control point

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of the Federal meat and poultry inspection regulations.

(d) Signing and dating the HACCP plan

(1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance

(ii) Upon any modification

(iii) At least annually, upon reassessment, as required under Section 417.4(a)(3) of the Federal regulations.

(e) Pursuant to Title 21 of the U.S. Code of Federal Regulations, 608 and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section or to operate in accordance with the requirements of the regulations may render the products produced under those conditions adulterated.

Section 417.7 Training

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of the Federal regulations, which could include adapting a generic model that is appropriate for the specific product

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of the Federal regulations.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Block 3—Plant Meets Regulatory Requirements?

Actions

Block 3

When the HACCP system regulations first apply to an establishment and, as appropriate, thereafter, inspection program personnel will perform Inspection System Procedure (ISP) 03A01 to determine whether an establishment has apparently complied with the requirements. (See the basic compliance checklist, FSIS Form 5000.1-1.)

Basic compliance checks–ISP procedures 01A01, 03A01, 05A01–focus on whether an establishment has failed to institute the system features required by FSIS regulations: i.e. either the establishment does not have a required plan or procedures or recordkeeping (for example, when an establishment does not have written SSOPs or written procedures for collecting samples for *E. coli* testing) or, what the establishment has clearly does not meet regulatory requirements (for example, when the SSOPs of an establishment do not identify which procedures are pre-operational procedures; or, when a HACCP plan does not list the critical limits to be met at each critical control point or does not identify the corrective action to be taken in response to a deviation from a critical limit at a critical control point).

When performing the basic compliance/noncompliance procedure, inspection program personnel are to use the basic compliance checklist to ensure compliance with the regulatory requirements. The regulatory requirements are included on the checklist in FSIS Directive 5000.1 II.B.

Decisions

After FSIS inspection program personnel establish whether a plant meets regulatory requirements, they should proceed to:

Block 7 if the plant plan meets regulatory requirements; or

Block 4 if one or more regulatory requirements have not been met.

Block 4—FSIS Takes Withholding Action

Finding noncompliance with requirements(s) in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied.

If noncompliance with requirements involves only a failure that the responsible establishment official can resolve effectively and immediately (for example, if the responsible establishment official did not sign or date the HACCP plan when required), before taking corrective steps, inspection program personnel are to provide establishment management with an opportunity to bring the establishment into compliance as set forth in FSIS Directive 5000.1 II.C.

Actions

Block 4

Any time noncompliance is found while performing the basic compliance procedure, it should be completely described on a Noncompliance Record (NR) FSIS Form 5400-4.

An IIC who determines that an establishment has failed to meet one or more of the requirements should take the following steps:

1. Advise establishment management orally of the findings on which the intended action is based and (as soon as possible and by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance findings(s)

2. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness"

   Identify all possibly adulterated livestock or poultry products as "U.S. Retained"

3. Notify the District Office of the actions(s) taken and, if the establishment does not initiate action immediately to bring itself into compliance:

   a. the District Manager (DM), who will assign a Compliance Officer (CO) and,

   b. in conjunction with the CO, develop a case file and take further action as appropriate.

Block 4—FSIS Takes Withholding Action

Decisions

FSIS will continue to withhold marks of inspection until the plant meets the regulatory requirements. FSIS inspection program personnel must determine when requirements have been met. After FSIS inspection program personnel establish that requirements have been met, they should proceed to:

Block 5	Plant Complies

Block 5—Plant Complies

Actions

Block 5

No further action is required by FSIS in this block. The withholding action imposed under Block 4 remains in effect until the plant complies with the HACCP regulations.

Decisions

If or when the noncompliance is corrected, FSIS inspection program personnel will proceed to:

Block 6 FSIS Removes Withholding Action

Block 6—FSIS Removes Withholding Action

Establishment is allowed to resume operation.

Actions

Block 6

When the plant is in compliance with HACCP regulatory requirements, FSIS will remove the withholding action and allow the plant to resume operations and proceed to:

Block 7 FSIS Performs Other Procedures

Block 7—FSIS Performs Other Procedures

FSIS Directive 5000.1 Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform procedures (ISP procedures 03B01 and 02 through 03J01 and 02) to verify the adequacy of an establishment's HACCP plan(s) by making determinations about compliance with regulatory requirements.

PBIS will schedule procedures, selecting either--

- a procedure for reviewing features of a HACCP plan in operation (for example, correlating records with random observation or measurement at a CCP), or
- a procedure for reviewing implementation of a HACCP plan for a particular product.

The objective of these activities is to determine whether, as documented in its records (§ 417.5), the establishment is complying with the requirements for implementation of a HACCP plan, including monitoring, verification, and corrective action requirements (§§ 417.2(c)(4) and (c)(6), 417.3, 417.4(a), and 417.5 and § 304.3(c) or § 381.22(c)), so that FSIS can make determinations about HACCP system adequacy (§ 417.6), including whether the system prevents the distribution of adulterated products that may endanger public health.

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain an adequate HACCP plan, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.) Similarly, finding Listeria monocytogenes in a ready-to-eat product or residues of an animal drug that are not within an applicable tolerance established under the Federal Food, Drug, and Cosmetic Act is evidence that a HACCP plan may be inadequate and, therefore, should be reassessed.

Block 7—FSIS Performs Other Procedures

B. Requirements

The particular ISP procedure may focus on one or more of the requirements addressed in this Paragraph III.B.

1. Establishment monitoring

a. The establishment is monitoring CCP's to ensure compliance with critical limits (§ 417.2(c)(4)).

b. Establishment records documenting the monitoring of CCP's include the recording of actual values (in terms of observations and times, temperatures, and/or other quantifiable limits in the HACCP plan) (§§ 417.2(c)(6) and 417.5(a)(3)).

2. Establishment verification

a. The establishment is verifying the implementation of its HACCP plan(s) by performing verification activities (§§ 417.2(c)(7) and 417.4(a)(2)).

b. Establishment records documenting verification activities include:

- but are not limited to, the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions, and the review of records generated and maintained in accordance with §417.5(a)(3).

- the review, prior to shipping product, of the records associated with the production of that product to ensure completeness. Where practicable, this review will be conducted, dated, and signed by an individual who did not produce the record(s).

(§§ 417.4(a)(2) and 417.5(c))

Block 7—FSIS Performs Other Procedures

c. If an establishment that slaughters cattle, swine, chickens, or turkeys has substituted an alternative frequency for the frequency of sampling for E. coli specified in § 310.25(a)(2)(iii) or § 381.94(a)(2)(iii), the alternative is an integral part of the establishment's verification procedures (paragraph (a)(2)(iv) of § 310.25 or § 381.94; see Part Four, Paragraph III.B.1.d.).

3. Deviations from critical limits

a. Corrective actions

(1) The HACCP plan assigns responsibility for taking corrective action (by, for example, specifying the establishment personnel who will perform various activities) (§ 417.3(a)).

(2) In response to a deviation from a critical limit for which a HACCP plan identifies the corrective action to be taken, the establishment followed the corrective action procedure(s) in the plan (§§ 417.2(c)(5) and 417.3(a)).

(3) The establishment's records document corrective action taken in response to a deviation from a critical limit, including procedure(s) to--

- o identify and eliminate the cause of the deviation,
- o bring the CCP under control,
- o establish measures to prevent recurrence, and
- o prevent distribution of product adulterated as a result of the deviation.

(§§ 417.3(a) and (c) and 417.5(a)(3))

b. Unforeseen hazards. In response to a deviation from a critical limit that a HACCP plan does not cover with a specific corrective action, the establishment's records document procedures used to segregate and hold affected product, at least until the establishment--

- o performed a review to determine the acceptability of affected product for distribution, and

- o when necessary, took action to ensure that product adulterated as a result of the deviation would not be distributed

(§§ 417.3(b) and (c) and 417.5(a)(3))

4. Plan reassessment and modification

a. Reassessment

(1) If a deviation that is not covered by a corrective action specified in a HACCP plan occurred, or another unforeseen hazard arose, the establishment reassessed the HACCP plan (§ 417.3(b)(4)).

(2) If a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding the applicable performance standard (in Table 2 of § 310.25(b)(1) or § 381.94(b)(1)) on the second consecutive series of FSIS tests for that product, the establishment reassessed the HACCP plan for that product (paragraph (b)(3)(ii) of § 310.25 or § 381.94).

(3) If there was a change that could affect the hazard analysis or alter a HACCP plan, the establishment reassessed the HACCP plan (§ 417.4(a)(3)).

b. Modification. If a plan reassessment revealed that a HACCP plan no longer meets the requirements in § 417.2(c), the establishment modified the HACCP plan (§ 417.4(a)(3)).

c. Training. The individual who performed the reassessment or modification of a HACCP plan meets the training requirements in § 417.7(b) (§§ 417.3(b)(4), 417.4(a)(3), and 417.7(a)(2)).

5. Records

a. HACCP plan support. Establishment records--

- o document the decisionmaking associated with the selection and development of CCP's and critical limits, including references to the basis (scientific or technical and/or regulation(s)) for each, and

Block 7—FSIS Performs Other Procedures

- o support the monitoring and verification procedures that the establishment has selected and the frequency with which the establishment conducts those procedures

(§ 417.5(a)(2))

b. Product identification. Establishment records document slaughter production lot, product code(s), product name, or other identifier (§ 417.5(a)(3)).

c. Authentication. Each entry on a record maintained under a HACCP plan--

- o is made at the time the specific event occurs,
- o includes the date and time that the entry was recorded, and
- o is signed or initialed by the establishment employee who made the entry

(§ 417.5(b))

(Note: Any other record required by § 417.5(a)(3) must include the date on which the record was made.)

d. Data integrity. The establishment has implemented controls to ensure data integrity for HACCP plan records maintained on computers (if any) (§ 417.5(d)).

e. Records review. Prior to shipping a product for distribution, the establishment's review of the records associated with the product's production (to ensure completeness) includes--

- o a determination that all critical limits were met, and
- o when appropriate, a determination that the establishment took corrective action(s), including the proper disposition of product

(§ 417.5(c))

Block 7—FSIS Performs Other Procedures

(Note: Where practicable, an individual who did not produce the records must conduct, date, and sign this review.)

f. Retention and availability

(1) The establishment retains records required by § 417.5(a)(3) for at least the following period(s):

- o 1 year for slaughter activities and for refrigerated product;
- o 2 years for product that is frozen, preserved, or shelf-stable

(§ 417.5(e)(1)).

(2) Records required by § 417.5(a)(3):

- o are on-site for at least 6 months, and
- o are available within 24 hours of an FSIS employee's request if stored off-site after 6 months

(§ 417.5(e)(2))

(Remember, the specific retention period and location requirements do not apply until the date on which an establishment must comply with the HACCP system regulations.)

Block 7—FSIS Performs Other Procedures

Actions

Block 7

Inspection program personnel will perform procedures (ISP procedures 03B01 and 02 through 03J01 and 02) to verify the adequacy of an establishment's HACCP plan(s) by making determinations about compliance with regulatory requirements.

PBIS will schedule procedures, selecting either--

- a procedure for reviewing features of a HACCP plan in operation (for example, correlating records with random observation or measurement at a CCP), or
- a procedure for reviewing implementation of a HACCP plan for a particular product.

The objective of these activities is to determine whether, as documented in its records (§ 417.5), the establishment is complying with the requirements for implementation of a HACCP plan, including monitoring, verification, and corrective action requirements (§§ 417.2(c)(4) and (c)(6), 417.3, 417.4(a), and 417.5 and § 304.3(c) or § 381.22(c)), so that FSIS can make determinations about HACCP system adequacy (§ 417.6), including whether the system prevents the distribution of adulterated products that may endanger public health.

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain an adequate HACCP plan, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.) Similarly, finding Listeria monocytogenes in a ready-to-eat product or residues of an animal drug that are not within an applicable tolerance established under the Federal Food, Drug, and Cosmetic Act is evidence that a HACCP plan may be inadequate and, therefore, should be reassessed.

Block 7—FSIS Performs Other Procedures

Decisions

Whenever inspection program personnel perform a procedure in the Inspection System Procedure (ISP) guide, whether scheduled or unscheduled, they either do or do not find noncompliance with one or more regulatory requirements.

Upon completion of an inspection procedure(s), FSIS inspectors will proceed to:

Block 8	determine whether a noncompliance exists

[Note: Further discussion regarding procedures 01 and 02 may be found under Block 10B, page 28, of this document.]

Block 8—Noncompliance Found?

Noncompliance is the failure to meet any HACCP requirement. To determine noncompliance, inspection program personnel should use what is known to them as a fact and what is reasonable to assume. In making a determination, inspection program personnel must assess their observations, analyze the facts, and decide which performance standards or regulatory requirements apply.

Actions

Block 8

Decisions

Upon completion of an inspection procedure(s), FSIS inspectors will proceed to:

Block 9	if a noncompliance is found to determine whether a System Failure exists, or
Stop	when noncompliance with regulatory requirements is not found, the procedure is recorded as "performed" on the Procedure Schedule (PS). FSIS sampling is recorded as "performed" as well.

Block 9—System Failure?

1. Has the establishment met the basic regulatory requirements? That is, if the establishment is not implementing all or some of its program, it has not met the basic regulatory requirements. For example, if an establishment is not maintaining **any** records associated with its HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify its HACCP plan when it no longer meets the requirements---then the establishment has not met the regulatory requirements. Therefore, inspection program personnel are unable to make the determination that the establishment is not producing adulterated product, and therefore the HACCP system is inadequate. In these cases, the HACCP system would be considered inadequate for not meeting the Basic regulatory requirements. This noncompliance would be documented under the Basic procedure code 03A01.

   The determination of an inadequate system in this case could be accomplished by performing the 01 or 02 procedure.

2. Was adulterated product produced or shipped?

   The IIC has determined that the HACCP system did not prevent the production and distribution of adulterated product. The establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per Section 417.3 of the Federal regulations. If inspection program personnel are able to make this determination, and the establishment has performed its pre-shipment review, then the HACCP system is inadequate.

   The determination of an inadequate system in this case could only be accomplished by performing the 02 procedure. It should be kept in mind that inspection program personnel could have performed the 02 procedure in response to noncompliance found during the 01 procedure.

Block 9—System Failure?

3. Is there a trend in establishment noncompliance?

   Inspection program personnel should observe trends in the noncompliance classification indicators marked on NRs when determining whether an establishment's HACCP system is inadequate. If two or more NR's have the same noncompliance classification indicators marked and if descriptions of noncompliance indicate that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate. Because there will be a great variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily support an inadequate system. Therefore, inspection program personnel must thoroughly analyze and document noncompliance trends that may support a determination.

   When reviewing a possible trend in incidents of noncompliance, inspection program personnel must closely review the descriptions of noncompliance contained in Block 10 of the NR form. Inspection program personnel should not solely rely on the number of marked noncompliance classification indicators. Only through careful analysis of written descriptions of noncompliance can inspection program personnel determine whether there is a trend indicating that a HACCP system may be inadequate.

   To adequately identify and track trends, inspection program personnel should document incidents of noncompliance, even if found and corrected by the establishment at a later step in the process. For example, if inspection program personnel observe that a designated establishment employee has failed to monitor a critical limit as specified within a HACCP plan, the incidence of noncompliance should be documented in an NR, even if the establishment also has discovered and corrected this noncompliance during verification.

4. Did the establishment review the records associated with production of the product? This review should have included determination that all critical limits were met and, if appropriate, corrective actions were taken, including proper disposition of product.

   If the establishment has not performed the pre-shipment review, then it has not met the regulatory requirements Section (417.5(c)of the Federal regulations). In such cases, inspection program personnel are unable to make the determination that the establishment is not producing adulterated product, and therefore the HACCP system is inadequate.

   The determination of an inadequate system in this case could only be accomplished by performing the 02 procedure.

Block 9—System Failure?

Actions

Block 9

When noncompliance with requirements is found, FSIS inspection program personnel will proceed to:

Block 10	in situations where noncompliance has been determined but there is not a system failure; or
Block 11	if the IIC has documented that a HACCP system did not prevent the production and distribution of adulterated product the violations include failures to comply with requirements for monitoring for CCP's, to respond to deviations from critical limits, and to document verification and review of production records.

Block 10—FSIS Completes Noncompliance Report

Recording Noncompliance

All noncompliance will be documented on a Noncompliance Record (NR) with NR Continuation Sheet(s) attached as appropriate. The most appropriate trend indicator will be marked on the NR.

Describing the Noncompliance

Noncompliance must be accurately described in Block 10 of the NR. The NR is an official record used by the inspector to document noncompliance. All information related to the noncompliance must be included when describing the noncompliance. Because NRs may be used to support an enforcement action, they must be written in a manner that will allow anyone reading the narrative to accurately visualize the noncompliance. If additional space is needed to describe a noncompliance, an NR Continuation Sheet should be used, and a notation to that effect should be made in Block 10. NR Continuation sheets should be attached, as appropriate.

Supporting Information

When documenting noncompliance, it is important to reference supporting documentation. The regulatory requirement that was not met must always be cited (for example, Section 417.3). The documentation should include the page and/or part number of the establishment's HACCP plan when the plan requirements are not met. The date and the name and/or number of the plant record must always be cited when describing any noncompliance connected with HACCP records. To adequately identify trends in noncompliance, it is important that the description include the date and number of related NRs. Also, it should be noted what corrective actions were taken in response to the related incidences of noncompliance and whether or not the failure of those corrective actions contributed to the current noncompliance.

A Noncompliance Record, FSIS Form 5400.5-4, serves as FSIS official record of noncompliance with one or more regulatory requirements. (As stated on the NR: "This document serves as written notification of your failure to comply with regulatory requirement(s), which could result in additional regulatory and administrative action.")

Block 10—FSIS Completes Noncompliance Report

Actions

Block 10

If the inspector is not able to determine that there is a system failure, the enforcement action is taken in accordance with Part Three of FSIS Directive 5000.1 III.C. 2. The inspector should:

- take official control action as appropriate
- advise establishment management by providing a copy of the NR that documents the noncompliance finding(s) as soon as possible and no later than the end of the tour of duty and give management an opportunity to respond
- complete documentation of establishment action(s) to bring the establishment into compliance (see FSIS Directive 5400.5)
- notify the DO if the establishment does not bring itself into compliance

Until an establishment is in compliance with the regulatory requirements(s) that resulted in issuance of an NR, the NR is "open". Inspection program personnel should review the file of "open" NRs daily

Inspection program personnel who find noncompliance with one or more regulatory requirements should also (1) categorize the noncompliance by marking the appropriate PS and NR indicator, and (2) document followup and their findings, using an NR.

It is the purpose of trend indicators to improve the ability of FSIS to evaluate establishment performance and process control by providing information on trends in noncompliance. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance. Inspection program personnel must mark the indicator that best describes the noncompliance

Decisions

FSIS inspector completes NR for noncompliance and proceeds to:

Block 10A	Plant Management Responds

Block 10A—Plant Management Responds

Actions

Provide establishment management with an opportunity to respond to the NR, either orally or in writing. Block 12 of the NR–immediate action(s)–is used to show action the establishment is taking to correct the noncompliance that resulted in issuance of the NR, including appropriate product disposition. Block 13–further planned action(s)–is used to show action the establishment plans to take to bring itself into compliance with regulatory requirements; such action should include measures to prevent recurrence.

Inspection program personnel need to determine that the immediate and further planned actions bring the establishment back into compliance with regulatory requirements. **Official control action will be maintained if the inspector cannot determine from the identified actions that the plant is in compliance with regulatory requirements.**

When an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an NR, inspection program personnel should file the NR as "closed"

Block 10A.

Decisions

FSIS proceeds to:

Block 10B.	FSIS Performs 02 Procedure, if appropriate.

Block 10B—FSIS Performs 02 Procedure, If Appropriate

Procedures 01 and 02

Because some of the requirements have records associated with them, both the 01 and 02 procedures have two components–**review and observation** and **recordkeeping review**. Both the 01 and 02 procedures can be used to verify each of the five features of HACCP systems. The method used to perform the procedure is **one** difference between them.

The 01 procedure is used to review at **random** the HACCP plan features in operation. Using the review and observation or recordkeeping component, any combination of the requirements can be randomly verified. It would be equally appropriate to focus on one feature specifically while performing the 01 procedure. For example, an inspector may decide to observe a plant employee measuring a critical limit and recording the result. The inspector may then measure the critical limit and compare his or her finding with the limit that the employee recorded. The inspector may also review CCP records for a different lot or lots of product or calibration records before considering the procedure complete.

The 02 procedure is used to **verify all requirements.** The 02 procedure focuses on the system in operation by making determinations about whether the establishment is following the HACCP plan: establishment personnel perform tasks in the plan, corrective actions are taken, and pre-shipment review prevents distribution of adulterated product for a given lot or shipment. For 02, inspection program personnel can use review and observation or recordkeeping review.

It is important to point out that because the 01 procedure is **random**, it is performed to determine whether the plant meets the HACCP regulatory requirements. Because the 02 procedure applies to an entire given lot or shipment, inspection program personnel are additionally determining whether the HACCP system worked.

In this procedure while the product is being produced, the inspector will verify each CCP, each CCP verification activity performed, the corrective action (if any) taken in response to a deviation, any reassessment conducted in response to a deviation, and the pre-shipment review for that specific production lot. The 02 procedure is not considered complete until after the inspector has verified the establishment's pre-shipment review. Therefore, performing the 02 procedure may be time-consuming, depending on the process.

If, while performing the 01 procedure, inspection program personnel determine noncompliance with the HACCP regulatory requirements, inspection program personnel should further verify whether the plan prevented adulterated product from being shipped. To make such verification, inspection program personnel will perform an 02 procedure **any time** noncompliance is found on an 01

Block 10B—FSIS Performs 02 Procedure, If Appropriate

procedure. When performing the 02 procedure, inspection program personnel should focus on very specific parts of the requirements.

Actions

Block 10B

Decisions

If an 02 procedure is performed, proceed to:

Block 8 to determine whether a Noncompliance exists.

Block 11—FSIS Completes Noncompliance Report and Takes Official Control Action (Withhold)

Recording Noncompliance

All noncompliance will be documented on an NR with NR Continuation Sheet(s) attached, as appropriate. The most appropriate trend indicator will be marked on the NR.

Describing the Noncompliance

Noncompliance must be accurately described in block 10 of the NR. The NR is an official record used by the inspector to document noncompliance. All information related to the noncompliance must be included when describing the noncompliance. Because NRs may be used to support an enforcement action, they must be written in a manner that will allow anyone reading the narrative to accurately visualize the noncompliance. If additional space is needed to describe a noncompliance, an NR Continuation Sheet should be used, and a notation to that effect should be made in block 10. NR Continuation sheet(s) should be attached, as appropriate.

Supporting Information

When documenting noncompliance, it is important to reference supporting documentation. The regulatory requirement that was not met should always be cited (for example, Section 417.3). The page and/or part number of the establishment's HACCP plan must be included when the plan requirements are not met. The date and the name and/or number of the plant record must always be cited when describing any noncompliance connected with HACCP records. To adequately identify trends in noncompliance, it is important that the description include the date and number of related NRs. Also, it should be noted what corrective actions were taken in response to the related incidences of noncompliance and whether or not the failure of those corrective actions is responsible for the current noncompliance.

Block 11—FSIS Completes Noncompliance Report and Takes Official Control Action (Withhold)

Actions

Finding noncompliance with requirements(s) in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied.

1. Establishment management should be advised orally of the findings on which the intended action is based

2. a. The inspector should refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness"

   b. All possibly adulterated livestock or poultry products must be identified as "U.S. Retained"

Decisions

FSIS inspector completes NR for system failure and proceeds to:

Block 12	IIC contacts the District Office.

Block 12—IIC Contacts the District Office

It is important to reiterate that inspection program personnel are to contact the **District Office** in cases of a withholding action due to a system failure.

Actions

Block 12

Notify the DO of actions taken.

Decisions

FSIS inspector proceeds to:

Block 13	District assigns CO

Block 13—District Assigns CO

Actions

Block 13

The DM will assign a CO, who will visit the establishment and initiate a case file.

Decisions

Go To Block 14	IIC/CO review situation

Block 14—IIC/CO Review Situation

Actions

Block 14

When inspection program personnel have documented noncompliance or linkages between several noncompliances that demonstrate a systems failure for HACCP, a Compliance Officer will visit the plant and establish a case file. To ensure that this occurs, inspection program personnel will call the District Office. The District Office will contact a Compliance Officer, who will visit the plant as soon as possible.

Once the Compliance Officer arrives at the plant, he or she will review the Noncompliance Record files to develop a case history. This history will aid the District Manager in deciding whether to either sustain current action or take further regulatory action.

When the Agency proceeds with regulatory action, the case file is presented as official evidence. All documentation must be written so that legal authorities can understand the seriousness of the noncompliance. Because documentation must support regulatory actions, documentation is important. The Compliance Officer will go through documentation looking for linkages or recurring noncompliance to prove that the plant does not have proper control over its processes. The Compliance Officer will stress these points in the case file.

In addition to the documents, the Compliance Officer will take a statement from the inspector. This is important because it establishes the inspector as a field expert. It allows the thought process to be captured in writing for legal authorities to review and understand without interviewing the inspector at the time of the review. The statement also demonstrates that inspection program personnel are working within the scope of their employment if later indemnification occurs. It should be kept in mind that the Compliance Officer needs the help of inspection program personnel to build a case.

Go To Block 15 FSIS Determines Action(s)

Block 15—FSIS Determines Action(s)

Actions

Block 15

Suspension and withdrawal actions are subject to Department and Agency supplementary guidelines and rules of practice. Inspection program personnel will receive specific instructions on appropriate in-plant controls on a case-by-case basis from the District Office.

Decisions

Go To Block 16	FSIS advises plant management in writing

Block 16—FSIS Advises Plant in Writing

Actions

Block 16

The DM notifies the plant of the enforcement actions from this point.

Decisions

Go To Block 17	FSIS pursues regulatory action(s)

Block 17—FSIS Pursues Regulatory Action(s)

Actions

Block 17

Regulatory actions are subject to Department and Agency rules of practice. Inspection program personnel will receive specific instructions on appropriate in-plant controls on a case-by-case basis from the District Office.

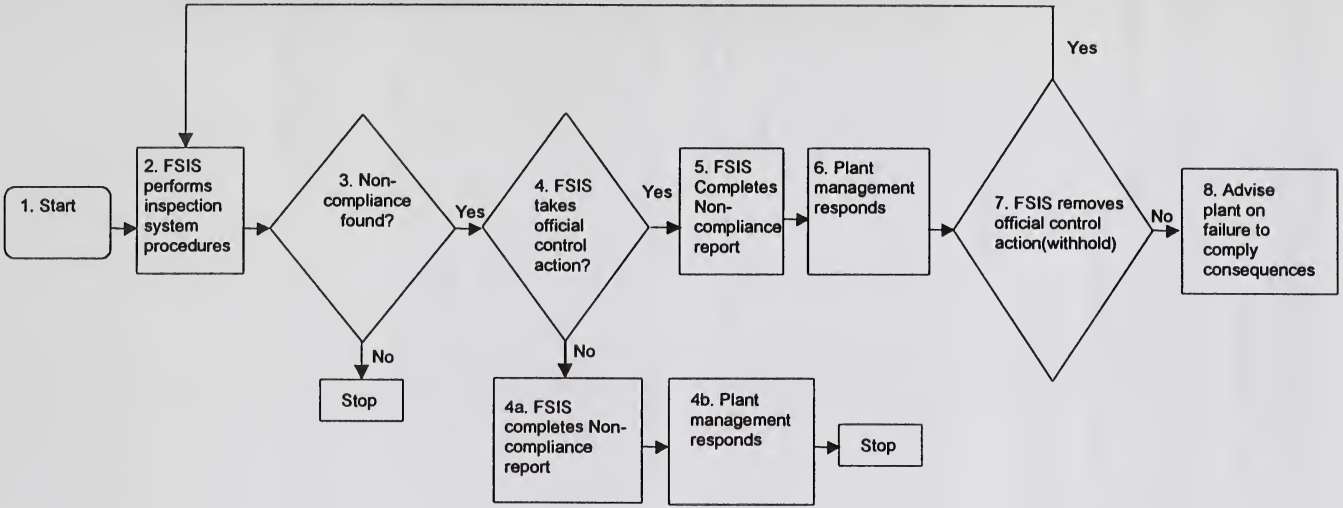
Other Consumer Protection

At this time, regulatory requirements for other consumer protection activities such as misbranding or economic adulteration have not changed. The Deficiency Classification Guide will no longer be used in establishments subject to the Pathogen Reduction/HACCP regulations. The Compliance/Noncompliance Determination Guide covers all areas of FSIS regulatory responsibility. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance.

Industry must prevent contamination and adulteration and comply with other FSIS regulations. When contamination or adulteration occurs, the establishment management has the responsibility to bring the establishment into compliance by controlling the immediate situation and preventing recurrence of the problem. Actions that do not accomplish both are inadequate. Adulterated or misbranded product must not be produced but, if contamination or adulteration occurs, corrective actions must be taken to prevent the product from being distributed and preventive measures must be taken to prevent recurrence.

FSIS will continue to have responsibility for ensuring that adulterated product does not enter commerce, even if such adulterated product is not a food safety hazard. For example, if product identified as "Bologna", made with beef and chicken, is being labeled as "Beef Bologna", inspection program personnel would initiate official control actions, document the noncompliance on an NR, and mark the "Misbranding" trend indicator on the Procedure Schedule (PS) and the Noncompliance Record. In other situations, official control actions might not be necessary, but the noncompliance would still be recorded on an NR and given to management as notification of the failure to comply with regulatory requirements. For example, if unused equipment and supplies were stored on the ground outside the plant and a mouse is seen running under the equipment, the "outside premises" trend indicator would be marked on the PS and NR. The noncompliance would be documented on the NR and given to plant management as notification of failure to meet regulatory requirements. The establishment is responsible for bringing itself into compliance with regulatory requirements. The establishment actions should address proper product disposition and measures to prevent recurrence. Documentation of recurring or repeated noncompliance with regulatory requirements may be used as a basis for further FSIS actions.

Regulatory Process For **Other** Consumer Protection Activities



FSIS DIRECTIVE 5000.1

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

ENFORCEMENT OF REGULATORY REQUIREMENTS IN ESTABLISHMENTS SUBJECT TO THE HACCP SYSTEM REGULATIONS
(including regulations on Sanitation SOP's, E. coli Testing and Criteria, and Salmonella Performance Standards)

PART ONE--GENERAL

I. PURPOSE

To further the goal of reducing the risk of foodborne illness from meat and poultry products to the maximum extent possible, FSIS issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule in July 1996. As amended by that rule, FSIS's regulations require establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur. These regulations are the framework for a modernized approach to inspection that relies less on after-the-fact detection of problems and more on verifying the effectiveness of processes and process controls designed to assure food safety (that is, the establishment's system for assuring food safety).

This directive provides instructions to inspection program personnel for reviewing an establishment's HACCP plan and otherwise enforcing the HACCP system regulations (9 CFR part 417). It also updates previous instructions to inspection program personnel regarding the regulations on Sanitation Standard Operating Procedures (SOP's) (9 CFR part 416). In addition, this directive addresses actions based on noncompliance with the E. coli process control verification requirements in establishments that slaughter cattle, swine, chickens, or turkeys (9 CFR 310.25(a) and 381.94(a)) and the pathogen reduction performance standards for Salmonella in establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey (9 CFR 310.25(b) and 381.94(b)).

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD, Import Offices

Inspection program personnel are to follow the instructions in this directive in every establishment that is subject to the HACCP system regulations and, for enforcement of the E. coli process control verification requirements, in other official establishments as well. For enforcement of the Sanitation SOP regulations in establishments that are not yet subject to the HACCP system regulations, inspection program personnel should continue to follow the instructions in FSIS Directive 11,100.3, Amend 2, "Evaluating, Verifying, and Enforcing Sanitation Standard Operating Procedure Requirements."

II. [Reserved]

III. REASON FOR ISSUANCE

As of late January 1998, 1999, or 2000, depending upon establishment size (see Part Two, Paragraph I.A.), official establishments must comply with HACCP system requirements (part 417) and establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey are subject to the pathogen reduction performance standards for Salmonella (§310.25(b) and 381.94(b)).

FSIS is issuing this directive to--

- o provide instructions for enforcing the HACCP system regulations (Part Two),
- o update the instructions previously issued for enforcing the regulations on Sanitation SOP's (Part Three) and E. coli testing and criteria (Part Four), and
- o address enforcement of the Salmonella pathogen reduction performance standards.

This directive also provides information on how to integrate these activities with other inspection program procedures.

IV. REFERENCES

Regulations: §§ 304.3(c), 310.25 (Attachment 1), 312.6, 381.22(c), 381.94 (Attachment 1), and 381.99, and parts 416 (Attachment 1) and 417 (Attachment 1).

Directives: FSIS Directive 5400.5, "Inspection System Activities" and FSIS Directive, 8800.2, "Performance-Based Inspection System: Overview of Policies and Implementing Procedures"

V. ABBREVIATIONS AND FORMS

CO-- an FSIS compliance officer
CS-- an FSIS circuit supervisor

DO-- the appropriate Field Operations district office
IIC-- the inspector in charge
ISP-- inspection system procedure(s), as compiled in the ISP Guide
NR-- Noncompliance Record, FSIS Form 5400-3
PBIS-- the performance-based inspection system (see FSIS Directive 8800.2)

FSIS Form 5000-1--	HACCP Systems Basic Compliance Checklist (Attachment 2)
FSIS Form 5000-2--	Sanitation SOP's--Basic Compliance Checklist (Attachment 3)
FSIS Form 5000-3--	E. coli Testing--Basic Compliance Checklist (Attachment 4)
FSIS Form 5000-4--	E. coli Testing Checklist--Regulatory Requirements (§ 310.25 or §381.94) Other Compliance/Noncompliance (Attachment 5)

VI. OVERVIEW

This directive addresses the types of determinations that FSIS expects inspection program personnel to make routinely in establishments that are subject to the HACCP system regulations. It specifies the procedures in the ISP that focus on whether or not particular requirements in the regulations on HACCP systems, Sanitation SOP's, E.coli testing and criteria, and Salmonella performance standards are met. When inspection program personnel conducting these procedures determine there has been a failure or failures to comply with regulatory requirements, they are to document their findings on a NR (as instructed in FSIS Directive 5400.5).

In this directive, possible failures to comply with food safety-related regulations are divided into two categories: (1) basic compliance/noncompliance; and (2) compliance/noncompliance with other requirements. This directive does not address the Agency's other consumer protection activities, such as economic adulteration or misbranding. Those requirements remain the subject of procedures in the ISP Guide (see FSIS Directive 5400.5 and attachments and FSIS Directive 8800.2 and attachments). The Agency also is limiting the application of the following FSIS directives to establishments that are not subject to the HACCP system regulations: 5400.1 and 5400.2 (Inspection System Guide and updating procedures); 8800.1 (PBIS implementation); 8800.3 (updating establishment/shift monitoring plans); 8810.1 (plant profile instructions); 6350.1 (trimming, vacuuming, and other carcass interventions); 6540.1 (antimicrobial use of TSP); 7310.4 (foreign particle contamination); 8820.1 (corrective action system); 8821.1 (boneless meat reinspection); 8830.1 (progressive enforcement action); and 11,100.3 (Sanitation SOP requirements).

Basic compliance/non-compliance focuses on establishment failures to institute the systems required by FSIS regulations and includes types of noncompliance for which FSIS has specified the appropriate enforcement action to be initiated by the inspection program personnel who find these failures. For compliance/non-compliance determinations regarding other food safety regulatory requirements, FSIS decisionmaking on how and when to act generally will take into account additional information on establishment performance. This does not, however, limit or otherwise effect other appropriate actions that inspection program personnel take to protect the public health (including the use of official marks and devices to prevent distribution of adulterated products).

PART TWO--HACCP SYSTEMS

I. GENERAL

A. Applicability of Regulations

The HACCP system regulations (part 417) apply in all official establishments as of the following dates:

January 26, 1998, in an establishment with 500 or more employees ("large establishment");

January 25, 1999, in an establishment with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than $2.5 million) ("smaller establishment"); and

January 25, 2000, in an establishment with fewer than 10 employees or annual sales of less than $2.5 million ("very small establishment").

FSIS will begin making compliance determinations pursuant to this directive as of the date the HACCP system regulations apply in a particular establishment.

B. Regulatory Overview

FSIS views a HACCP system as essential in carrying out an establishment's responsibility to comply with regulatory requirements and prevent the distribution of adulterated products. FSIS's position is that failure to develop and implement a HACCP plan that complies with §417.2 or failure to operate in accordance with part 417 requirements may render products produced under those conditions adulterated (pursuant to FMIA sections 8 and 21 or PPIA sections 7 and 14)
(§ 417.2(e)).

Inspection program personnel will perform procedures to verify the adequacy of an establishment's HACCP plan(s) by determining that each plan meets the requirements of part 417 and other applicable food safety regulations (§ 417.8).

FSIS may find an establishment's HACCP system to be inadequate if:

- o the HACCP plan in operation does not meet the requirements in part 417 (§ 417.6(a));
- o establishment personnel are not performing tasks specified in the HACCP plan (§ 417.6(b));
- o the establishment fails to take corrective actions, as required by § 417.3 (§ 417.6(c));
- o records are not maintained (as required in §417.5) (§ 417.6(d)); or
- o adulterated product is produced or shipped (§ 417.6(e)).

C. Terminology

For purposes of the HACCP system regulations:

"corrective action"-- procedures to be followed when a deviation occurs;

"critical control point" (CCP)--a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level;

"critical limit"-- the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard;

"food safety hazard" or "hazard"-- any biological, chemical, or physical property that may cause a food to be unsafe for human consumption;

"HACCP system"-- the HACCP plan in operation, including the HACCP plan itself;

"preventive measure"-- physical, chemical, or other means that can be used to control an identified food safety hazard;

"process-monitoring instrument"-- an instrument or device used to indicate conditions during processing at a critical control point; and

"responsible establishment official"-- the individual with overall authority on-site or a higher level official of the establishment

(§ 417.1).

II. BASIC COMPLIANCE/NONCOMPLIANCE

A. General

When the HACCP system regulations first apply to an establishment and as appropriate thereafter, inspection program personnel will perform a procedure (ISP procedure 03A01) to determine whether or not an establishment has complied with the requirements addressed in Paragraph II.B. of this part. (See the basic compliance checklist, FSIS Form 5000-1.)

B. Requirements

1. Hazard analysis and HACCP plan development

a. Initial hazard analysis. The establishment conducted a hazard analysis or had a hazard analysis conducted for it (§ 417.2(a)).

(1) The hazard analysis includes food safety hazards that are reasonably likely to occur in the production process (before, during, and after entry into the establishment) and (when there are any) it identifies the preventive measures the establishment can apply to those food safety hazard(s).

(2) The hazard analysis includes a flow chart that describes (diagrams) the steps of each process and product flow in the establishment.

(3) The hazard analysis identifies the intended use or consumers of finished product(s).

b. Initial plan development

(1) If an establishment's hazard analysis revealed one or more food safety hazards that are reasonably likely to occur, the establishment has a written HACCP plan for each of its products (at the time commercial production begins) (§ 417.2(b)(1); § 304.3(c) or § 381.22(c)). (A HACCP plan must be developed by an individual who satisfies the training requirements in § 417.7(b) (§ 417.7(a)(1)); see Paragraph III.B.3.c. of this part.)

(Note: It is possible (though unlikely) that a hazard analysis conducted in accordance with § 417.2(a) will reveal no food safety hazards that are reasonably likely to occur. FSIS is

not aware of any meat or poultry production process that one can say, categorically, poses no likely hazards.)

(2) The establishment conducted validation activities to determine that a HACCP plan is functioning as intended, and the establishment's records--

- o include multiple results that verify the monitoring of CCP's and conformance with critical limits, and
- o after each deviation from a critical limit (if any), demonstrate subsequent results that support the adequacy of corrective action(s) in achieving control at the CCP.

(§§ 417.2(c)(4), 417.3(a)(2), and 417.4(a)(1)).

c. Subsequent analysis and plan development

(1) Hazard analysis reassessment. If, after an establishment's hazard analysis revealed no food safety hazards that are reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists, the establishment reassessed the adequacy of the hazard analysis (§417.4(b)). (Examples of changes that might have such an effect: raw materials or raw materials' source, product formulation, slaughter or processing methods or systems, production volume, personnel, packaging, finished product distribution system, or intended use or consumers of finished product.)

(2) New product

(a) Before producing a new product for distribution, the establishment--

- o conducted a hazard analysis (or had a hazard analysis conducted for it), and
- o has an applicable HACCP plan for the product.

(b) If the establishment began distributing a new product more than 90 days ago, it has validated the HACCP plan that covers the new product.

(§ 304.3(c) or § 381.22(c))

2. Contents of HACCP plan(s)

a. Multiple products. If a HACCP plan covers more than one product, the products are all within one of the nine processing categories specified in § 417.2(b)(1) (§ 417.2(b)(2)).

b. Food safety hazard(s). The HACCP plan lists the food safety hazard(s) identified in the hazard analysis (§ 417.2(c)(1)). (These are the food safety hazards that must be controlled for each process.)

Exception: A HACCP plan for thermally processed/commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X, need not address food safety hazards associated with microbiological contamination (§417.2(b)(3)).

c. Hazard control

(1) The HACCP plan lists CCP's for each food safety hazard (§ 417.2(c)(2)).

(2) The HACCP plan lists critical limits to be met at each CCP (§ 417.2(c)(3)).

d. Monitoring. The HACCP plan lists the procedures to be used to monitor each CCP and the frequency with which these procedures will be performed (§ 417.2(c)(4)).

e. Corrective actions. The HACCP plan identifies the corrective action to be followed in response to a deviation from a critical limit at a CCP (§ 417.2(c)(5)).

f. Verification procedures. The HACCP plan lists the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed (§ 417.2(c)(7)).

3. Recordkeeping. The HACCP plan's recordkeeping system documents the monitoring of CCP's and includes records with the actual values and observations (§ 417.2(c)(6)).

4. Dated signature

a. Acceptance and reassessment. The responsible establishment official has signed and dated the HACCP plan--

- o upon initial acceptance (§ 417.2(d)(1)), and
- o at least annually thereafter upon required plan reassessment (§ 417.4(a)(3))

(§ 417.2(d)(2)(i) and (d)(2)(iii)).

(Note: To determine whether a year has elapsed, use the date on which the HACCP system regulations apply to an establishment (January 26, 1998; January 25, 1999; or January 25, 2000) as day one of the first year.)

b. Modification. If the HACCP plan was modified, the responsible establishment official signed and dated the plan (§ 417.2(d)(2)(ii)).

C. Enforcement Actions

Finding noncompliance with requirement(s) addressed in Paragraph II.B. of this part in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied. Inspection program personnel who determines that an establishment has failed to meet one or more of these requirements is to take the following steps:

1. Advise establishment management orally of the findings on which the intended action is based and (as soon as possible where practicable and by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. a. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness."

b. Identify all possibly adulterated livestock and/or poultry products as "U.S. Retained."

3. Notify the DO of the action(s) taken, and if the establishment does not initiate action immediately to bring itself into compliance,

- o notify the DO (which will assign a CO) and,
- o in conjunction with the CO, develop a case file and take further action as appropriate.

Note: If noncompliance with Paragraph II.B. requirements involves only a failure that the responsible establishment official can cure effectively and immediately (for example, the

responsible establishment official did not sign and/or date the HACCP plan when required), then before taking these steps, inspection program personnel are to provide establishment management with an opportunity to bring the establishment into compliance.

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform procedures (ISP procedures 03B01 and 02 through 03J01 and 02) to verify the adequacy of an establishment's HACCP plan(s) by making determinations about compliance with regulatory requirements.

PBIS will schedule procedures, selecting either--

- a procedure for reviewing features of a HACCP plan in operation (for example, correlating records with random observation or measurement at a CCP), or
- a procedure for reviewing implementation of a HACCP plan for a particular product.

The objective of these activities is to determine whether, as documented in its records (§ 417.5), the establishment is complying with the requirements for implementation of a HACCP plan, including monitoring, verification, and corrective action requirements (§§ 417.2(c)(4) and (c)(6), 417.3, 417.4(a), and 417.5 and § 304.3(c) or § 381.22(c)), so that FSIS can make determinations about HACCP system adequacy (§ 417.6), including whether the system prevents the distribution of adulterated products that may endanger public health.

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain an adequate HACCP plan, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.) Similarly, finding Listeria monocytogenes in a ready-to-eat product or residues of an animal drug that are not within an applicable tolerance established under the Federal Food, Drug, and Cosmetic Act is evidence that a HACCP plan may be inadequate and, therefore, should be reassessed.

B. Requirements

The particular ISP procedure may focus on one or more of the requirements addressed in this Paragraph III.B.

1. Establishment monitoring

a. The establishment is monitoring CCP's to ensure compliance with critical limits (§ 417.2(c)(4)).

b. Establishment records documenting the monitoring of CCP's include the recording of actual values (in terms of observations and times, temperatures, and/or other quantifiable limits in the HACCP plan) (§§ 417.2(c)(6) and 417.5(a)(3)).

2. Establishment verification

a. The establishment is verifying the implementation of its HACCP plan(s) by performing verification activities (§§ 417.2(c)(7) and 417.4(a)(2)).

b. Establishment records documenting verification activities include:

- but are not limited to, the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions, and the review of records generated and maintained in accordance with §417.5(a)(3).
- the review, prior to shipping product, of the records associated with the production of that product to ensure completeness. Where practicable, this review will be conducted, dated, and signed by an individual who did not produce the record(s).

(§§ 417.4(a)(2) and 417.5(c))

c. If an establishment that slaughters cattle, swine, chickens, or turkeys has substituted an alternative frequency for the frequency of sampling for E. coli specified in § 310.25(a)(2)(iii) or § 381.94(a)(2)(iii), the alternative is an integral part of the establishment's verification procedures (paragraph (a)(2)(iv) of § 310.25 or § 381.94; see Part Four, Paragraph III.B.1.d.).

3. Deviations from critical limits

a. Corrective actions

(1) The HACCP plan assigns responsibility for taking corrective action (by, for example, specifying the establishment personnel who will perform various activities) (§ 417.3(a)).

(2) In response to a deviation from a critical limit for which a HACCP plan identifies the corrective action to be taken, the establishment followed the corrective action procedure(s) in the plan (§§ 417.2(c)(5) and 417.3(a)).

(3) The establishment's records document corrective action taken in response to a deviation from a critical limit, including procedure(s) to--

- o identify and eliminate the cause of the deviation,
- o bring the CCP under control,
- o establish measures to prevent recurrence, and
- o prevent distribution of product adulterated as a result of the deviation.

(§§ 417.3(a) and (c) and 417.5(a)(3))

b. Unforeseen hazards. In response to a deviation from a critical limit that a HACCP plan does not cover with a specific corrective action, the establishment's records document procedures used to segregate and hold affected product, at least until the establishment--

- o performed a review to determine the acceptability of affected product for distribution, and
- o when necessary, took action to ensure that product adulterated as a result of the deviation would not be distributed

(§§ 417.3(b) and (c) and 417.5(a)(3))

4. Plan reassessment and modification

a. Reassessment

(1) If a deviation that is not covered by a corrective action specified in a HACCP plan occurred, or another unforeseen hazard arose, the establishment reassessed the HACCP plan (§ 417.3(b)(4)).

(2) If a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding the applicable performance standard (in Table 2 of § 310.25(b)(1) or § 381.94(b)(1)) on the second consecutive series of FSIS tests for that product, the establishment reassessed the HACCP plan for that product (paragraph (b)(3)(ii) of § 310.25 or § 381.94).

(3) If there was a change that could affect the hazard analysis or alter a HACCP plan, the establishment reassessed the HACCP plan (§ 417.4(a)(3)).

b. Modification. If a plan reassessment revealed that a HACCP plan no longer meets the requirements in § 417.2(c), the establishment modified the HACCP plan (§ 417.4(a)(3)).

c. Training. The individual who performed the reassessment or modification of a HACCP plan meets the training requirements in § 417.7(b) (§§ 417.3(b)(4), 417.4(a)(3), and 417.7(a)(2)).

5. Records

a. HACCP plan support. Establishment records--

- document the decisionmaking associated with the selection and development of CCP's and critical limits, including references to the basis (scientific or technical and/or regulation(s)) for each, and
- support the monitoring and verification procedures that the establishment has selected and the frequency with which the establishment conducts those procedures

(§ 417.5(a)(2))

b. Product identification. Establishment records document slaughter production lot, product code(s), product name, or other identifier (§ 417.5(a)(3)).

c. Authentication. Each entry on a record maintained under a HACCP plan--

- o is made at the time the specific event occurs,
- o includes the date and time that the entry was recorded, and
- o is signed or initialed by the establishment employee who made the entry

(§ 417.5(b))

(Note: Any other record required by § 417.5(a)(3) must include the date on which the record was made.)

d. Data integrity. The establishment has implemented controls to ensure data integrity for HACCP plan records maintained on computers (if any) (§ 417.5(d)).

e. Records review. Prior to shipping a product for distribution, the establishment's review of the records associated with the product's production (to ensure completeness) includes--

- o a determination that all critical limits were met, and
- o when appropriate, a determination that the establishment took corrective action(s), including the proper disposition of product

(§ 417.5(c))

(Note: Where practicable, an individual who did not produce the records must conduct, date, and sign this review.)

f. Retention and availability

(1) The establishment retains records required by § 417.5(a)(3) for at least the following period(s):

- o 1 year for slaughter activities and for refrigerated product;
- o 2 years for product that is frozen, preserved, or shelf-stable

(§ 417.5(e)(1)).

(2) Records required by § 417.5(a)(3):

- o are on-site for at least 6 months, and
- o are available within 24 hours of an FSIS employee's request if stored off-site after 6 months

(§ 417.5(e)(2))

(Remember, the specific retention period and location requirements do not apply until the date on which an establishment must comply with the HACCP system regulations.)

C. Enforcement Actions

1. Finding noncompliance with requirements addressed in Paragraph III.B. of this part in and of itself supports the withholding of inspection only when:

- o inspection program personnel have documented that a HACCP system did not prevent the production and distribution of adulterated product (and not including economic adulteration), and
- o the violations include failures to comply with requirements for monitoring of CCP's, to respond to deviations from critical limits, and to document verification and review of production records.

Under these circumstances, the Inspection program personnel should take the same steps as in cases of basic noncompliance (see Paragraph II.C.).

2. In other situations, the Inspection program personnel is to--

- o take official control action as appropriate,
- o advise establishment management by providing a copy of the NR that documents the noncompliance finding(s),
- o review and verify documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5), and
- o decide whether the establishment's noncompliance history warrants the involvement of a CO, and if so, seek CO involvement through the DO, participate with the CO in the

development of a case file, and take further action as appropriate.

PART THREE--SANITATION SOP'S

I. GENERAL

A. Applicability of Regulations

The Sanitation SOP regulations (part 416) apply in all official establishments.

B. Regulatory Overview

FSIS views Sanitation SOP's as essential to operating and maintaining an establishment in accordance with sanitary practices to prevent the distribution of adulterated products. Failure to comply with part 416 requirements may result in an FSIS determination that the conditions in an establishment are such that livestock product or poultry product is adulterated (because it is unsound, unhealthful, unwholesome, or otherwise unfit for human food or has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health).

Inspection program personnel will perform procedures to verify the adequacy and effectiveness of an establishment's Sanitation SOP's (including the procedures specified in the Sanitation SOP's) by determining that they meet part 416 requirements (§ 416.17).

C. Terminology

As used in this directive:

"pre-operational procedures" refers to the procedures in an establishment's Sanitation SOP's that the establishment is to conduct daily before it begins operations; and

"during-operations procedures" refers to the procedures in an establishment's Sanitation SOP's that the establishment is to conduct daily during its operations.

II. BASIC COMPLIANCE/NONCOMPLIANCE

A. General

As appropriate, inspection program personnel will perform a procedure (ISP procedure 01A01) to determine whether or not an establishment has complied with the requirements addressed in Paragraph II.B. of this part (basic compliance checks). (See the basic compliance checklist, FSIS Form 5000-2.)

B. Requirements

1. Sanitation SOP's

a. The establishment has written Sanitation SOP's that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product(s) (§ 416.12(a)). (These procedures must be sufficient to prevent direct contamination or adulteration of product(s); see Paragraph III.B.2. of this part.)

b. The Sanitation SOP's identify which of the procedures are pre-operational procedures (§ 416.12(c)).

c. The pre-operational procedures address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils (§ 416.12(c)).

d. The Sanitation SOP's specify the frequency with which the establishment will conduct each procedure (§ 416.12(d)).

e. The Sanitation SOP's identify the establishment employee or employees responsible for implementing and maintaining specified procedures (§ 416.12(d)).

2. Recordkeeping. The establishment has identified records that, on a daily basis, document implementation and monitoring of the Sanitation SOP's and any corrective actions taken (§ 416.16(a)).

3. Dated signature. The individual with overall authority on-site or a higher level official of the establishment has signed and dated the Sanitation SOP's

- upon initial implementation, and
- upon any modification

(§ 416.12(b)).

C. Enforcement Actions

Finding noncompliance with requirement(s) addressed in Paragraph II.B. of this part in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied. Inspection program personnel who determine that an establishment has failed to meet one or more of these requirements is to take the following steps

1. Advise establishment management orally of the decision to withhold inspection and (as soon as possible and where practicable by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. a. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness."

b. Identify all possibly adulterated livestock and/or poultry products as "U.S. Retained."

c. Identify violative equipment, utensil(s), room(s), or compartment(s) as "U.S. Rejected."

3. Notify the DO of the action(s) taken and, if the establishment does not initiate action immediately to bring itself into compliance

- o notify the DO (which will assign a CO), and,
- o in conjunction with the CO, develop a case file and take further action as appropriate.

Note: If noncompliance with Paragraph II.B. requirements involves only the failure of the individual with overall authority on-site, or a higher level official of the establishment, to sign and/or date the Sanitation SOP's, then before taking these steps, are to provide establishment management with an opportunity to bring the establishment into compliance.

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform procedures (ISP procedures 01B01 and 02 and 01C01 and 02, to verify the adequacy and effectiveness of an establishment's Sanitation SOP's (including the procedures specified in the Sanitation SOP's) by making determinations about compliance with § 416.11 through § 416.16 requirements.

PBIS will schedule procedures, selecting either

- o a records procedure for reviewing the Sanitation SOP's themselves and the daily documentation of the establishment's implementation of those procedures and required corrective actions, or
- o a procedure for direct observation of the establishment's implementation of Sanitation SOP procedures and required

corrective actions, assessment of sanitary conditions, and review of related records.

The objective of these activities is to determine whether, as documented in the establishment's records (§ 416.16), an establishment is complying with the requirements for

- o implementation of Sanitation SOP's, including monitoring of implementation (§ 416.13),
- o routine evaluation of the effectiveness of Sanitation SOP's (§§ 416.12(a) and 416.14), and
- o taking corrective action(s) (§ 416.15).

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain sanitary conditions, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.)

B. Requirements

The particular ISP procedure may focus on one or more of the requirements addressed in this Paragraph III.B.

1. Sanitation SOP implementation

a. The establishment conducts pre-operational procedures before it begins operations (§ 416.13(a)).

b. The establishment conducts during-operations procedures at the frequencies specified in its Sanitation SOP's (§ 416.13(b)).

c. The establishment monitors daily the implementation of procedures in its Sanitation SOP's (§ 416.13(c)).

2. Corrective actions. When (as determined by the establishment or by FSIS) the establishment's Sanitation SOP's--or the procedures specified therein or their implementation or maintenance--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to

- o ensure the appropriate disposition of products that may be contaminated,

- o restore sanitary conditions, and
- o prevent recurrence of direct product contamination or adulteration, including appropriate reevaluation and modification of Sanitation SOP procedure(s) or appropriate improvements in the execution of Sanitation SOP procedure(s)

(§ 416.15).

3. Sanitation SOP effectiveness

a. The establishment's Sanitation SOP's are sufficient to prevent direct contamination or adulteration of product(s) (§ 416.12(a)).

b. The establishment

- o routinely evaluates the effectiveness of the procedures in its Sanitation SOP's in preventing direct contamination or product adulteration, and
- o revises the procedures in its Sanitation SOP's when necessary to keep them effective and current with respect to changes in its facilities, equipment, utensils, operations, or personnel

(§ 416.14)

4. Records

a. Daily documentation. The establishment's daily records document

- o implementation of its Sanitation SOP's,
- o monitoring of its Sanitation SOP's, and
- o corrective actions taken (if any)

(§ 416.16(a)).

b. Authentication. The establishment's records are initialed and dated by the establishment employee identified in the Sanitation SOP's as responsible for implementing and monitoring specified procedure(s) (§ 416.16(a)).

c. Data integrity. The establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any) (§ 416.16(b)).

d. Retention and availability

(1) The establishment retains records required by part 416 for at least 6 months.

(2) Records required by part 416

- are on-site for at least 48 hours, and
- are available within 24 hours of an FSIS employee's request if stored off-site after 48 hours.

(§ 416.16(c))

C. Enforcement Actions

1. Finding noncompliance with requirements addressed in Paragraph III.B. of this part in and of itself supports the withholding of inspection when inspection program personnel have repeatedly documented that an establishment's Sanitation SOP's did not prevent the same type of direct contamination or adulteration of product(s) and, hence, the violations include failure to comply with requirements for corrective actions that prevent recurrence of direct product contamination or adulteration by appropriate reevaluation and modification (maintenance) or appropriate improvements in the execution of Sanitation SOP procedure(s).

Under these circumstances, inspection program personnel should take the same steps as in cases of basic noncompliance (see Paragraph II.C.).

2. In other situations, the IIC is to

- take official control action as appropriate,
- advise establishment management by providing a copy of the NR that documents the noncompliance finding(s),

- o review and verify documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5), and

- o decide whether the establishment's noncompliance history warrants the involvement of a CO, and if so, seek CO involvement through the DO, participate with the CO in the development of a case file, and take further action as appropriate.

PART FOUR--E. COLI TESTING AND CRITERIA

I. GENERAL

A. Applicability of Regulations

The E. coli regulations (§§ 310.25(a) and 381.94(a)) apply in any official establishment that slaughters any market class of cattle, swine, chickens, or turkeys.

B. Regulatory Overview

FSIS regulations require E. coli testing as an ongoing, objective process control indicator for fecal contamination. To evaluate the results, FSIS is establishing performance criteria to reflect the prevalence and levels of E. coli on carcasses produced nationwide. FSIS intends these criteria as an initial basis for using microbial testing to evaluate the adequacy of establishment process controls.

There currently are performance criteria for evaluating the results of E. coli testing of--

- o cattle and swine, when samples are collected by excising (§ 310.25(a)(5)(i), Table 1), and

- o chickens (§ 381.94(a)(5)(i), Table 1).

E. coli performance criteria are not regulatory standards. Test results that do not meet applicable criteria indicate that an establishment may not be maintaining process controls sufficient to prevent fecal contamination (paragraph (a)(6) of §§ 310.25 and 381.94)).

Until FSIS establishes performance criteria for evaluating the results, establishments testing cattle and swine that collect samples by sponging carcasses and establishments testing turkeys must use statistical process control techniques (paragraph (a)(5)(ii) of §§ 310.25 and 381.94). (Statistical process control involves initial data evaluation to determine process capability -- the typical process performance level or baseline level-- and then checking subsequent data to see whether they are consistent with the baseline

level to ensure the process is in control and variations are within normal and acceptable limits. Statistical process control techniques are used to check for unreasonably high results, trends, etc. and to look for and correct problems in a process.)

Inspection program personnel will perform a procedure to determine whether or not an establishment is complying with § 325.10(a) or § 381.94(a).

C. Terminology

For purposes of the E. coli regulations, "E. coli" is Escherichia coli Biotype I (§ 310.25(a)(1) or § 381.94(a)(1)).

II. BASIC COMPLIANCE/NONCOMPLIANCE

A. General

As appropriate, inspection program personnel will perform a procedure (ISP procedure 05A01) to determine whether or not an establishment has complied with the requirements set out in Paragraph II.B. of this part. (See the basic compliance checklist, FSIS Form 5000-3).

B. Requirements

1. Sampling procedures

a. The establishment has written procedures for collecting samples for E. coli testing.

b. The establishment's procedures identify the establishment employee(s) designated to collect samples for E. coli testing.

c. The establishment's procedures address

- the location(s) of sampling,
- how sampling randomness is achieved, and
- handling of samples to ensure sample integrity.

(Paragraph (a)(2)(i) of § 310.25 or § 381.94)

2. Sample collection. The establishment collects samples for E. coli testing (paragraph (a)(1) of § 310.25 or § 381.94). (Note: An establishment that slaughters more than one type of livestock or poultry or slaughters both livestock and poultry must test for E. coli in the type that it slaughters in the greatest number.)

3. Recordkeeping. The establishment records the analytical results of E. coli tests on a process control chart or table (paragraphs (a)(1)(iii) and (a)(4) of § 310.25 or § 381.94).

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform a procedure (ISP procedure 05A02) for making determinations about compliance with the requirements addressed in Paragraph III.B. of this part. (See the other compliance/noncompliance checklist, FSIS Form 5000-4).

When PBIS schedules the procedure, inspection program personnel will review sample collection procedures, observe collection, and/or review records of test results.

The objective of these activities is to determine whether or not an establishment is complying with the requirements for

- collecting and analyzing samples for E. coli (paragraphs (a)(1)(i), (a)(1)(ii), (a)(2)(ii) through (a)(2)(v), and (a)(3) of § 310.25 or § 381.94), and
- recording E. coli test results (paragraph (a)(4) of § 310.25 or § 381.94,

and whether the establishment is evaluating test results (paragraph (a)(5) of § 310.25 or § 381.94).

B. Requirements

1. Sample collection

a. The establishment collects samples from the type of livestock or poultry that it slaughters in the greatest number (paragraph (a)(1) of § 310.25 or § 381.94).

b. The establishment selects carcasses randomly (paragraphs (a)(1)(i), (a)(2)(i), and (a)(2)(ii) of § 310.25 or § 381.94). In particular, the technique in the establishment's procedures should achieve randomness, when the establishment follows its collection procedures.

c. The establishment collects samples

- at the required location in the process, and
- by the procedure specified in the regulations.

(paragraph (a)(2)(ii) of § 310.25 or § 381.94)

d. The establishment collects samples at the required frequency (paragraph (a)(1)(i) and paragraph (a)(2)(iii), (a)(2)(iv), or (a)(2)(v) of § 310.25 or § 381.94). Either

- o the establishment collects samples at the frequency specified in paragraph (a)(2)(iii) or, in a very low volume establishment, paragraph (a)(2)(v); or
- o if the establishment has substituted an alternative frequency for the frequency specified in paragraph (a)(2)(iii)--
  - (1) the alternative is an integral part of the verification procedures for a validated HACCP plan (see Part Two, Paragraph III.B.1.b.), and
  - (2) FSIS has not determined (and so notified the establishment in writing) that the alternative frequency is inadequate to verify the effectiveness of its processing controls.

(paragraph (a)(2)(iv) of § 310.25 or § 381.94)

e. Is there a reason, other than one or more specific points noted above, to question the integrity of the samples collected by the establishment, or is there other evidence indicating that the results obtained by the establishment may be inaccurate or unreliable for purposes of § 310.25(a) or § 381.94(a)?

In particular, does available information suggest that the establishment's written procedures and/or its practices are inadequate to ensure proper handling in collecting, storing, and transporting samples (for example, failure to use aseptic techniques when collecting samples; improper identification of samples; improper refrigeration of samples; prolonged holding of samples before shipment to a laboratory) or that the carcasses tested were treated differently than other carcasses?

(Remember, FSIS's "Guidelines for E. coli Testing for Process Control Verification in Raw Meat and Poultry" is guidance--not regulatory requirements.)

2. Sample analysis. The establishment obtains test results in accordance with the sample analysis requirements (paragraphs (a)(1)(ii) and (a)(3) of § 310.25 or § 381.94).
(Note: Only address this point when records or other information on analytical methodology is available.)

3. Test results

a. The establishment records the results of all E. coli testing on a process control chart or table that shows

- o at least the most recent 13 test results,
- o in terms of cfu/cm^2 of surface area sponged or excised or cfu/ml of rinse fluid by type of animal slaughtered

(paragraph (a)(4) of § 310.25 or § 381.94)

b. The establishment uses the results of E. coli testing, as follows:

- o when Table 1 does not include applicable m/M criteria, the establishment uses a statistical process control technique (charting or plotting the results over time) to determine what variation in test results is within normal limits;
- o when Table 1 includes applicable m/M criteria, the establishment determines whether it is operating within these criteria

(paragraph (a)(5) of § 310.25 or § 381.94)

c. The establishment retains records of test results for 12 months (paragraph (a)(4) of § 310.25 or § 381.94). (Note: The testing requirement has applied since January 25, 1997. However, under the frequency rule for very low volume establishments, no sampling was required until the first full week of operation after June 1, 1997.)

IV. ENFORCEMENT ACTIONS

A. General

When FSIS finds that an establishment is not complying with one or more provisions of § 310.25(a)(1) through (a)(4) or proceedings (paragraph (a)(7) of § 310.25 or § 381.94). Inspection program personnel initiate this process by notifying an establishment that they have determined the establishment is not complying with provision(s) of paragraph (a)(1), (a)(2), (a)(3), and/or (a)(4) of § 310.25 or § 381.94.

Test results that do not meet applicable m/M criteria (Table 1, paragraph (a)(5) of § 310.25 or § 381.94) indicate that an establishment may not be maintaining process controls

sufficient to prevent fecal contamination (paragraph (a)(6) of § 310.25 or § 381.94). In such situations, FSIS will take further action as appropriate to ensure that applicable provisions of the law are met. The IIC provides the DO with the information needed to determine whether and what further action (if any) to take.

B. Actions

1. Inspection program personnel who determines that an establishment has failed to meet one or more of the requirements addressed in Paragraph II.B. or Paragraph III.B. is to advise establishment management orally of the findings on which the intended action is based and (as soon as possible and by the end of the tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. If an IIC finds noncompliance with provision(s) of paragraph (a)(1), (a)(2), (a)(3), and/or (a)(4) of § 310.25 or § 381.94 and the establishment does not initiate action immediately to bring itself into compliance

- o notify the DO (which will assign a CO), and,
- o in conjunction with the CO, develop a case file and take further action as appropriate.

Margaret OK Glavin
Deputy Administrator
Office of Policy, Program Development
and Evaluation

§ 310.25 Contamination with microorganisms; pathogen reduction performance standards for Salmonella.

(a) Criteria for verifying process control; E. coli testing.

(1) Each official establishment that slaughters cattle and/or swine shall test for Escherichia coli Biotype 1 (E. coli). Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) Sample collection. The establishment shall collect samples from all chilled swine or cattle carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples shall be collected by either sponging or excising tissue from three sites on the selected carcass. On cattle carcasses, establishments shall sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments shall take samples by sponging from inside the flank, inside the brisket, and inside the rump; on swine carcasses, establishments shall sponge or excise tissue from the ham, belly and jowl areas.[1]

---

[1]A copy of FSIS's "Guidelines for E. coli Testing for Process Control verification in Cattle and Swine Slaughter Establishments" is available for inspection in the FSIS Docket Room.

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the volume of production at the following rates:
Cattle: 1 test per 300 carcasses, but at a minimum one sample each week of operation.
Swine: 1 test per 1000 carcasses, but at a minimum one sample each week of operation.

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and, (B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 20,000 swine, or a combination of cattle and swine not exceeding 6,000 cattle and 20,000 total of both types. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by

---

[2]A copy of the current edition/revision of the "Official Methods of AOAC International," 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical

a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm^2 of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) Criteria for evaluation of test results.

(i) An establishment excising samples from carcasses is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1 - EVALUATION OF E. coli TEST RESULTS

Type of Livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Cattle	negative	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000 CFU/cm^2	13	3

[a] Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 cfu/cm^2 carcass surface area.

Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417.

(ii) Establishments sponging carcasses shall evaluate E. coli test results using statistical process control techniques.

(6) Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) Failure to test and record. Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a)(1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standard; Salmonella.

(1) Raw meat product performance standards for Salmonella. An establishment's raw meat products, when sampled and tested by FSIS for Salmonella, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	N.A.[b]	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) Enforcement. FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

§ 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; E. coli testing.

---

[3] A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(1) Each official establishment that slaughters poultry shall test for Escherichia coli Biotype I (E. coli). Establishments that slaughter more than one type of poultry and/or poultry and livestock, shall test the type of poultry or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) Sample collection. Samples shall be collected by taking a whole bird from the end of the chilling process, after the drip line, and rinsing it in an amount of buffer appropriate to the type of bird being tested. If the bird is boned before chilling (hot boned poultry), the sample shall be taken from the end of the slaughter line instead of the end of the drip line.[1]

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but at a minimum one sample per each week of operation.
Turkeys: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation

---

[1]A copy of FSIS's "Sampling Technique for E. coli in Raw Meat and Poultry for Process Control Verification" is available for inspection in the FSIS Docket Room.

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys or a combination of chickens and turkeys not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments slaughtering turkeys in the largest number shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against

---

[2]A copy of the current edition/revision of the "Official Methods of AOAC International," 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be [2] A copy of the current edition/revision of the "Official Methods of AOAC International," 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417.

the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) Criteria for Evaluation of test results. An establishment is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1 - EVALUATION OF E. coli TEST RESULTS

Types of Poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Chickens	100 CFU/ml	1,000 CFU/ml	13	3
Turkeys	N.A.[a]	N.A.	N.A.	N.A.

[a] Not available; values for turkeys will be added upon completion of data collection program for turkeys.

(ii) For types of poultry appearing in paragraph (a)(5)(i) Table 1 of this section that do not have m/M criteria, establishments shall evaluate E. coli test results using statistical process control techniques.

(6) Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) Failure to test and record. Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a)(1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standards; Salmonella.

(1) Raw poultry product performance standards for Salmonella.

(i) An establishment's raw poultry products, when sampled and tested by FSIS for Salmonella as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Broilers	20.0% [b]	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	N.A.[b]	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; baseline targets for turkeys will be added upon completion of the data collection programs for that product.

(2) Enforcement. FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

PART 416--SANITATION

§ 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§ 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

§ 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§ 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;
(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417--HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;

(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter--all species.

(ii) Raw product--ground.

(iii) Raw product--not ground.

(iv) Thermally processed--commercially sterile.

(v) Not heat treated--shelf stable.

(vi) Heat treated--shelf stable.

(vii) Fully cooked--not shelf stable.

(viii) Heat treated but not fully cooked--not shelf stable.

(ix) Product with secondary inhibitors--not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment: and,

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point.

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 608 and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in

accordance with the requirements of this part, may render the products produced under those conditions adulterated.

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by § 417.3 of this part;

(d) HACCP records are not being maintained as required in § 417.5 of this part; or

(e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency Verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

FSIS DIRECTIVE 5000.1
Attachment 2

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
HACCP SYSTEMS -- BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS
PRODUCTS COVERED BY PROCESS		
IMPLEMENTATION DATE	NEW PRODUCT	REASSESSMENT DATE *(Yearly: Check for dated signature only)*

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Two, Paragraph II.B.

	REQUIREMENT	YES (✓)
1. HAZARD ANALYSIS AND HACCP PLAN DEVELOPMENT	**INITIAL HAZARD ANALYSIS** (§ 417.2(a)) The establishment has not conducted a hazard analysis or had a hazard analysis conducted for it.	
	The hazard analysis does not include food safety hazards that are reasonably likely to occur in the production process, or	
	does not identify the preventive measures the establishment can apply to those food safety hazard(s)	
	The hazard analysis does not include a flow chart that describes (diagrams) the steps of each process and product flow in the establishment.	
	The hazard analysis does not identify the intended use or consumers of finished product (s).	
	INITIAL PLAN DEVELOPMENT (§ 417.2 (c)(4), § 417.3(a)(2), and § 417.4(a)(1)) The establishment's hazard analysis revealed one or more food safety hazards that are reasonably likely to occur, and the establishment does not have a written HACCP plan for each of its products § 417.2 (b) (1); § 304.3 (c) or § 381.22 (c)).	
	The establishment has not conducted validation activities to determine that a HACCP plan is functioning as intended. The establishment's records do not include multiple results that verify the monitoring of CCP's and conformance with critical limits, or	
	after a deviation from a critical limit (if any), subsequent results that support the adequacy of corrective action (s) in achieving control at the CCP.	
	SUBSEQUENT ANALYSIS AND PLAN DEVELOPMENT HAZARD ANALYSIS REASSESSMENT After an establishment's hazard analysis revealed no food safety hazards that are reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists, the establishment did not reassess the adequacy of the hazard analysis (§ 417.4 (b)).	
	NEW PRODUCT (§ 304.3 (c) or § 382.22 (c)) (1) Before producing new product for distribution, the establishment did not conduct a hazard analysis (or have a hazard analysis conducted for it), or	
	did not have an applicable HACCP plan for the product.	
	(2) The establishment began distributing a new product more than 90 days ago, and it has not validated the HACCP plan that covers the new product.	

FSIS FORM 5000-1 (9/97)

FSIS FORM 5000-1 (9/97) (REVERSE)

	REQUIREMENT	YES (✓)
2. CONTENTS OF HACCP PLAN(S)	**MULTIPLE PRODUCTS** A HACCP plan covers more than one product and the products are not all within one of the nine processing categories specified in § 417.2 (b),(1) § 417.2 (b)(2).	
	FOOD SAFETY HAZARD(S) The HACCP plan does not list the food safety hazard(s) identified in the hazard analysis (§ 417.2 (c)(1)). (Exception: A HACCP plan for thermally processed/commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X, need not address food safety hazards associated with microbiological contamination (§ 417.2 (b)(3)).)	
	HAZARD CONTROL The HACCP plan does not list CCP's for each food safety hazard (§ 417.2(c)(2)).	
	The HACCP plan does not list critical limits to be met at each CCP (§ 417.2(c)(3)).	
	MONITORING The HACCP plan does not list the procedures to be used to monitor each CCP and the frequency with which these procedures will be performed (§ 417.2(c)(4)).	
	CORRECTIVE ACTIONS The HACCP plan does not identify the corrective action to be followed in response to a deviation from a critical limit at a CCP (§ 417.2 (c)(5)).	
	VERIFICATION PROCEDURES The HACCP plan does not list the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed (§ 417.2(c)(7)).	
3. RECORDKEEPING	The HACCP plan's recordkeeping system does not document the monitoring of CCP's and/or does not include records with the actual values and observations (§ 417.2 (c)(6)).	
4. DATED SIGNATURE	**ACCEPTANCE AND REASSESSMENT** (§ 417.2(d)) The responsible establishment official did not sign and date the HACCP plan (1) upon initial acceptance, or (2) at least annually thereafter upon required plan reassessment.	
	MODIFICATION The HACCP plan was modified, and the responsible establishment official did not sign and date the plan (§ 417.2(d) (2) (ii)).	

FSIS DIRECTIVE 5000.1
Attachment 3

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
SANITATION SOP'S -- BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.	IMPLEMENTATION DATE

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Three, Paragraph II.B.

	REQUIREMENT	YES (✓)
1. SANITATION SOP'S	The establishment does not have written Sanitation SOP's that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product(s) (§416.12(a)).	
	The Sanitation SOP's do not identify which of the procedures are pre-operational procedures (§416.12(c)).	
	The pre-operational procedures do not address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils (§416.12 (c)).	
	The Sanitation SOP's do not specify the frequency with which the establishment will conduct each procedure (§416.12 (d)).	
	The Sanitation SOP's do not identify the establishment employee or employees responsible for implementing and maintaining specified procedures (§416.12 (d)).	
2. RECORDKEEPING	The establishment does not have identified records that, on a daily basis, document implementation and monitoring of the Sanitation SOP's and any corrective actions taken (§416.16(a)).	
3. DATED SIGNATURE	The individual with overall authority on-site or a higher level official of the establishment did not sign and date the Sanitation SOP's (1) upon initial implementation, or	
	(2) upon a modification (§416.12 (d)).	

FSIS FORM 5000-2 (9/97)

FSIS Directive 5000.1
Attachment 4

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
E. COLI-- BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Four, Paragraph II.B.

	REQUIREMENT	(YES) (✓)
1. SAMPLING PROCEDURES	The establishment does not have written procedures for collecting samples for E. coli testing.	
	The establishment's procedures do not identify the establishment employee (s) designated to collect sample for E. coli testing. The establishment's procedures do not address	
	(1) the location(s) of sampling,	
	(2) how sampling randomness is achieved, or	
	3) handling of samples to ensure sample integrity. (Paragraph (a)(2)(i) of § 310.25 or § 381.94).	
2. SAMPLE COLLECTION	The establishment is not collecting samples for E. coli testing (Paragraph (a)(1) § 310.25 or § 381.94).	
3. RECORDKEEPING	The establishment is not recording the analytical results of E. coli tests on a process control chart or table (Paragraphs (a)(1)(iii) and (a)(4) of § 310.25 or § 381.94).	

FSIS FORM 5000-3 (9/97)

FSIS DIRECTIVE 5000.1
Attachment 5

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
***E. COLI* TESTING CHECKLIST - REGULATORY REQUIREMENTS**
(§310.25 OR §381.94) OTHER COMPLIANCE/NO COMPLIANCE

ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS

REQUIREMENT	YES (✓)
1. SAMPLE COLLECTION	
a. Livestock or poultry sampled *(paragraph (a)(1))* The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number	
b. Location and technique3 *(paragraph (a)(2)(ii))* The establishment is not collecting samples at the required location in the process.	
(1) The establishment is not collecting samples by: *(as applicable)* Sponging or excising tissue from the required sites on a livestock carcass, or whole-bird rinsing a chicken or turkey carcass, or sponging a turkey carcass	
c. Frequency (*paragraph* (a)(1)(l) and *paragraph* (a)(2)(iii), (a)92)(iv), or *(a)92)(v)).* (1) The establishment is not collecting samples at the frequency specified in paragraph (a) (2) (iii); or	
(2) In an establishment operating under a validated HACCP plan that has substituted and alternative for the specified frequency pursuant to paragraph (a) (2) (iv): (a) The alternative frequency is not an integral part of the establishment's HACCP plan verification procedures.	
(b) FSIS has determined *(and so notified the establishment in writing)* that the alternative frequency is inadequate to verify the effectiveness of its processing controls.	
d. random selection of *carcasses (paragraph (a)(1)(l), (a)(2)(l), and/or (a)(2)(ii))* (1) In selecting carcasses, the establishment is not following its written procedures on random sampling.	
(2) The establishment is not collecting samples randomly.	

FSIS Form 5000-4 (10/97)

FSIS Form 5000-4 (10/97) (REVERSE)

Requirement	YES (✓)
2. SAMPLE ANALYSIS ***(paragraph (a)(1)(ii) and (a)(3))***	
a. The laboratory analyzing the samples is not using an AOAC Official Method or another method that meets the criteria in *paragraph (a)(3).*	
3. RECORDS OF THEST RESULTS (paragraphs (a)(1)(iii) and (a) (4))	
a. The establishment's process control chart or table does not show at least the most recent 13 *E. coli* test results	
b. The establishment's process control chart or table does not express *E.coli* test results in terms of: (*as applicable*) cfu/cm^2 of surface area sponged or excised by type of livestock slaughtered, or cfu/ml of rinse fluid by type of poultry slaughtered.	
c. The establishment is not retaining records of test results for 12 months.	
4. Table 1 does not include applicable m/M criteria, and the establishment is not using a statistical process control technique *(charting or plotting the results over time)* to determine what variation in test results is within normal limits.	
5. Table 1 includes applicable m/M criteria, and the establishment is not determining whether it is operating within these criteria. *(An establishment is not operating within these criteria when the most recent test result exceeds M or when the number of samples out of the most recent 13 samples testing positive at levels above m is more than 3.)*	

FSIS DIRECTIVE 5000.1
Appendix A

SLAUGHTER PROCESS VERIFICATION METHODOLOGY

Hands-on verification of the pre-operational procedures component of a slaughter establishment's Sanitation SOP's will include utilization of a Pre-Operational Sanitation Inspection Plan. The development of a plan is necessary to provide uniformity in conducting pre-operational sanitation inspection by identifying areas and units for random sampling. Plans will differ with the size of the establishment: Establishments that have 15 or more units will be subdivided into areas and have a certain time allotment as compared to establishments that have 14 or less units, which will not be divided into areas and thus will have a shorter time allotment.

Pre-Op Sanitation Inspection Plans for Slaughter Establishments Having 15 Units or More

A Pre-Op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignments, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-up start time for each assignment:

   a. The pre-op start time will be determined by an Inspection program employee based on the Inspection Units (IU's) selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

   b. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate areas and identify units in each area:

   a. An area is a major portion of an establishment designated in the Pre-Op Sanitation Inspection Plan for hands-on pre-op sanitation inspection. Examples of an area include the picking area, the eviscerating area, or major equipment groupings or systems. The Inspection program employee will determine the boundaries of each area. One to five areas will be covered during a pre-op inspection assignment.

   b. Each area is divided into units. The size of an area may vary from 15 to 50 units. A unit is a numbered three-dimensional section within an area. Each unit must be sufficiently identified so that inspectors who rotate into a pre-op sanitation inspection assignment can easily identify each unit. A unit may have irregular boundaries that are usually identified by landmarks such as an individual piece of equipment, utensils, associated floors, walls, drains, or other vertical structures and overhead structures. A

hand-drawn schematic of the area will be used to identify units. The schematic will include major landmarks in the area such as walls, doors, and posts, and an outline of the principal equipment. The boundaries of the units will be drawn on the schematic and the units numbered. To the extent practical, units should be numbered in the order of product flow for each area. Large, complex equipment may be divided into smaller units. For example, a designated unit might be an individual piece of equipment, such as a picker, and the floor, gutter drain, posts walls, and overhead structures in the vicinity of that piece of equipment. The picker may also be divided down the middle and each half included in a different unit. Other examples of units include portions of the area with identifiable boundaries, such as the hide puller, including the floors, drains, walls, and overhead structures and a traffic lane through which products and personnel move.

c. Portable equipment and other equipment that is displaced during cleaning may not always be located entirely within a unit at the time of inspection. Such equipment will be inspected when it is within the boundaries of a unit.

d. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-Op Sanitation Inspection Plan.

e. Inspection Units (IU's) will be randomly selected from units in an area:

(1) Upon receipt of the Procedure Schedule (i.e., the week before), an Inspection program employee should select the random IU's for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but must be completed at least the day before hands-on verification is scheduled. This will allow determination of the lockout/tagout verification time based on the IU's selected. The selected IU's should remain under security. The amount of time for lockout/tagout verification should be communicated to the inspector(s) responsible for performing pre-operational sanitation.

The number of IU's to be selected for area sampling is according to the following schedule:

Units Per Area	Number of IU's
15 to 30	3
31 to 40	4
41 to 50	5

(2) The CS will authorize a method of randomly selecting IU's for inspection. The following method may be used:

(a) Number cardboard chips to correspond with the inspection unit numbers and place them in a container large enough to permit thorough mixing of the chips.

(b) Before each inspection, mix and then select the specified number of chips from the container.

(c) Write the IU numbers that have been selected for inspection on a piece of paper.

(d) Return the chips to the containers.

Pre-Op Sanitation Inspection Plans for Slaughter Establishments Having 14 Units or Less (small establishments)

Pre-op sanitation inspection in small establishments will differ from pre-op sanitation inspection in larger facilities. The Pre-Op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignment, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time:

a. An Inspection program employee will create a Pre-Op Sanitation Inspection Plan. The plan will be filed in the inspector's office or in a file designated for the inspector's use in those establishments that are not required to maintain an inspection office.

b. The pre-op start time will be determined by an Inspection program employee based on the IU's selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

c. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate units:

a. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-Op Sanitation Inspection Plan.

b. Small establishments will not be subdivided into areas.

c. An inspection program employee will select 3 IU's at random for pre-op sanitation inspection as scheduled by the PBIS.

d. An inspection program employee should select the random IU's upon receipt of the Procedure Schedule (i.e., the week before) for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but must be completed at least the day before hands-on verification is scheduled.

SUPPLEMENTARY INSTRUCTIONS REGARDING ENFORCEMENT ACTIONS

When noncompliance with regulatory requirement(s) is found, FSIS inspection program personnel will take action as outlined in FSIS Directive 5400.5 and FSIS Directive 5000.1, Part Three, and consistent with applicable regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").

Note: Hands-on verification includes a records review component. Prior to performing the hands-on verification, the inspector will review the establishment's records for that day, if available at that time. The inspector will document findings on FSIS Form 5400-4, Noncompliance Record (NR). When determining if noncompliance exists, you must take into account what is known for a fact. Therefore, if an establishment's records for that day are available, there may be something in the records that would make a difference in determining whether the establishment has failed to comply with one or more regulatory requirements. If the establishment's records for that day are not available, findings written on the establishment's records later will not be known as a fact when a determination is made by the inspector during the hands-on verification.

The regulations on Sanitation SOP's require the establishment to implement procedures sufficient to prevent direct contamination or adulteration of product(s), and pre-operational procedures in the Sanitation SOP's must address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils. Therefore, contaminated product and violative facilities, equipment, and utensils, in addition to requiring official control actions, will be considered Sanitation SOP failures. Official control action consists of retention of products and rejecting equipment, utensils, and rooms and/or areas to prevent their use in the production of products until a failure is remedied.

FSIS inspection program personnel will determine whether official control action is appropriate. When the Agency seeks to take further regulatory or administrative action, it must be able to rely on NR information. Therefore, documenting failure to comply with regulatory requirements as specified above is essential (whether or not official control action was taken).

FSIS Directive 5000.1
Appendix B

COMPLETING FSIS FORM 5400-4 WHEN MORE THAN ONE INSPECTOR PERFORMS SANITATION ISP PROCEDURES IN LARGE ESTABLISHMENTS

When multiple inspectors perform an individual ISP procedure, that is 01B or 01C, each inspector will document individual findings. This can be accomplished by one inspector, as consulted on the local level, documenting on the NR, while the remaining inspection program personnel utilize an NR Continuation Sheet for documentation purposes. ALL noncompliance with regulatory requirements must be documented. The NR Continuation Sheet(s) should have the same number as the NR.

The NR should include a statement to indicate the number of the NR Continuation Sheets that are attached. The NR Continuation Sheets will be attached and all the documentation will be provided to the plant manager. It is essential that the failure to comply with regulatory requirement(s), whether documented on the NR or the NR Continuation Sheet, include all information related to the noncompliance. It is important that both are written in a manner to allow "visualization" of the noncompliance. Both the NR and NR Continuation Sheet need to contain the provision(s) of the regulation(s) with which the establishment failed to comply as well as the section or page of the establishment's SSOP procedures not followed. Previous noncompliance for the "same root cause" should be included in the documentation and, as instructed in FSIS Directive 5400.5, noncompliance trend information provided. Also, the failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration as documented previously should be included.

Because NR information will form the basis of further Agency actions, it will be essential for each person documenting noncompliance with one or more regulatory requirements to include all of the above information.

For example: There are three inspectors at Est. 38 who perform Pre-op verification.

Two inspectors will document their findings on individual NR Continuation Sheets. One inspector documents failure to comply with regulatory requirement(s) on the NR. The NR and NR Continuation Sheets are put together, and the appropriate noncompliance and trend indicator blocks are marked on the NR and the Procedure Schedule. The NR will include a statement that there are two NR Continuation Sheets attached.

In our example, one of the inspectors documenting on an NR Continuation Sheet is responsible for pre-op verification on the slaughter floor. If this inspector finds repeated noncompliance for the "same root cause" on the slaughter floor, he or she is responsible for including this information on the NR Continuation Sheet (including previous PDR and NR numbers and dates). This inspector should also include failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration, as previously documented, and any notification he or she has previously provided to the establishment pertaining to the repeated failure to comply with regulatory requirement(s).

FSIS Directive 5400.5

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

INSPECTION SYSTEM ACTIVITIES

I. PURPOSE

FSIS is modernizing its approach to inspection to rely less on after-the-fact detection of problems and more on verifying the effectiveness of establishment processes and process controls. The Agency established the basic regulatory framework for this approach when it issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule (July 1996), which amended the regulations to require official establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur.

A modernized approach to inspection requires changes in the performance-based inspection system (PBIS) and the activities FSIS has conducted under that system--in particular, the tasks in the Inspection System Guide (ISG). Therefore, for establishments that are subject to the HACCP system regulations, FSIS is replacing the ISG and portions of the PBIS directives with this directive and its attachments. Inspection program personnel are to follow the instructions in this directive in every establishment that is subject to the HACCP system regulations.

II. [RESERVED]

III. REASON FOR ISSUANCE

FSIS is issuing this directive to provide procedures, forms, and instructions that are appropriate for use in a modernized inspection system.

In an official establishment, inspection program personnel are to follow the instructions in this directive (along with its attachments) if the establishment is subject to the HACCP system regulations.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD, Import Offices

OPI: OPPDE

FSIS Directive 5400.5

The HACCP system regulations apply in official establishments as of the following dates:

> January 26, 1998, in an establishment with 500 or more employees ("large establishment");
>
> January 25, 1999, in an establishment with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than $2.5 million) ("smaller establishment"); and
>
> January 25, 2000, in an establishment with fewer than 10 employees or annual sales of less than $2.5 million ("very small establishment").

In FSIS Directive 5000.1, "Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations," the Agency is providing instructions to inspection program personnel for enforcing the HACCP system regulations (9 CFR part 417), the regulations on Sanitation Standard Operating Procedures (SOP's) (9 CFR part 416), the E. coli process control verification requirements (in establishments that slaughter cattle, swine, chickens, or turkeys) (9 CFR 310.25(a) and 381.94(a)), and the pathogen reduction performance standards for Salmonella (in establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey) (9 CFR 310.25(b) and 381.94(b)).

The Agency also is limiting the application of the following FSIS directives to establishments that are not subject to the HACCP system regulations: 5400.1 and 5400.2 (Inspection System Guide and updating procedures); 8800.1 (PBIS implementation); 8800.3 (updating establishment/shift monitoring plans); 8810.1 (Plant Profile instructions); 6350.1 (trimming, vacuuming, and other carcass interventions); 6540.1 (antimicrobial use of TSP); 7310.4 (foreign particle contamination); 8820.1 (corrective action system); 8821.1 (boneless meat reinspection); 8830.1 (progressive enforcement action); and 11,100.3 (Sanitation SOP requirements).

IV. REFERENCES

Regulations: 9 CFR chapter III.
Directives: FSIS Directives 5000.1,"Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations" and FSIS Directive 8800.2, "Performance-Based Inspection System: Overview of Policies and Implementing Procedures."

V. ABBREVIATIONS AND FORMS

ADP-- automated data processing
CO-- an FSIS compliance officer
CS-- an FSIS circuit supervisor
DO-- the appropriate Field Operations district office
IIC-- the inspector in charge
IMDD-- Inspection Methods Development Division
ISP-- inspection system procedure(s), as compiled in the ISP Guide
NDG-- Noncompliance Determination Guide
NR-- Noncompliance Record
PBIS-- the performance-based inspection system (see FSIS Directive 8800.2)
PS-- Procedure Schedule
RDAD-- Regulations Development and Analysis Division, Office of Policy, Program Development and Evaluation

Attachment 1:
FSIS Form 5400-1 -- Plant Profile(HACCP)
Instructions for Completion

Attachment 2:
FSIS Form 5400-2 -- Procedure Schedule
FSIS Form 5400-3 -- Procedure Schedule (unscheduled)
FSIS Form 5400-3B -- Schedule Summary Sheet
Example of Form 5400-2
Example of Form 5400-3

Attachment 3:
FSIS Form 5400-4 -- Noncompliance Record
FSIS Form 5400-4a -- Noncompliance Record Continuation

Attachment 4:
FSIS Form 5400-5 -- Establishment/Shift Inspection

Procedure Worksheet HACCP
Est./Shift

Attachment 5:
Noncompliance Determination Guide

Attachment 6:
Inspection Systems Procedures

VI. OVERVIEW

A. PBIS

Two components of PBIS will guide inspection program activities. These components are designed for use in determining whether an establishment is complying with regulatory requirements--in particular, in making determinations about compliance with the HACCP system regulations (HACCP plan requirements and the adequacy of HACCP plans in operation), the regulations on Sanitation Standard Operating Procedures (SOP's), and other consumer protection requirements.

The first PBIS component is the ISP Guide, which includes all the in-plant "Procedures," grouped into the following "Activities": Sanitation SOP's (01);(02--Reserved); HACCP Systems (03); Economic/Wholesomeness (04); Sampling (05); Other Requirements (06); (07--Reserved); and Emergency Elements (08). The hierarchical categories in the ISP Guide are Activities, Elements, and Procedures; the most specific category is Procedures (comparable to Tasks in the ISG). Scheduling will be determined by frequency at the Procedure level.

The second PBIS component is the automated system that schedules work and incorporates the findings from conducting the procedures. The design of the automated system has several factors. These include the Activity-Element-Procedure structure, priority assignment parameters, frequency assignments, and time functions. (The automated system uses the current priority model, frequency rules, and time assignment parameters, where applicable.)

In operation, the automated system generates schedules for in-plant procedures and creates reports based on data entered into the ADP system. These data include documentation on procedures performed by inspection program personnel and information from inspection program personnel on establishment failure to comply with regulatory requirements and noncompliance trend indicators (PS's, FSIS Form 5400-2, and NR's and NR's Continuation Sheet, FSIS Form 5400-4 and FSIS Form 5400-4a, respectively). FSIS uses the reports in evaluating establishment noncompliance (including trends) and to support supervisory and

management decision making. (FSIS also provides a summary report to establishment management.)

B. Enforcement Policy

The distribution of adulterated or misbranded product is prohibited, and compliance with FSIS regulations is required. It is the responsibility of establishment management to prevent contamination and adulteration and, when it nevertheless occurs, to take actions that bring the establishment into compliance by controlling the immediate situation and preventing recurrence of the problem. Actions that do not accomplish both are inadequate. FSIS will take further action based on recurring or repeated noncompliance with regulatory requirements.

VII. ISP GUIDE

A. General

FSIS is issuing the ISP Guide to provide the in-plant procedures that the Agency currently views as appropriate in enforcing regulatory requirements and administering the inspection mandates. The ISP Guide lists the applicable regulatory requirements and FSIS directives. (To provide consistency in conducting the procedure for pre-operational sanitation in slaughter operations, Appendix A to FSIS Directive 5000.1 sets out the instructions for random selection of units within an establishment.)

B. Updating the ISP Guide

The Agency expects that as FSIS modernizes its system of food safety regulation, changes in these procedures will be necessary. In particular, the Agency's comprehensive regulatory review includes reconsideration of FSIS directives and procedures. As the Agency amends its regulations, it will modify related directives and procedures as appropriate. Implementation of ISP changes will accord with bargaining unit contractual requirements.

RDAD and IMDD are responsible for managing and coordinating development of ISP changes, which generally will occur in conjunction with rulemaking proceedings or other Agency policy issuances. Resolution of differences and clearance of draft ISP changes will be part of the regular policy review process for FSIS issuances.

RDAD will work with the Labor Management Relations staff to facilitate bargaining unit consideration of draft changes. RDAD will work with AISD on production, distribution, and integration of approved changes.

Agency personnel who believe changes are needed should make their suggestions, through regular supervisory channels, to their Deputy Administrators. Deputy Administrators should forward their recommendations to RDAD.

VIII. PLANT PROFILES

FSIS uses FSIS Form 5400-1 to collect information needed to implement and maintain PBIS and to update CORE files (Common On-line Reference for Establishments). See Attachment 1 for the instructions for completing this form.

IX. INSPECTION PROCEDURE WORKSHEETS

A. General

FSIS Form 5400-5 is the mechanism for updating the ADP component of PBIS. (The ADP system specifies ISP codes for each procedure.) FSIS Form 5400-2 is generated by the automated system in the DO.

Using FSIS Form 5400-5 the inspection program personnel develop, and then maintain, an establishment/shift procedure plan that reflects the current operations for one shift in a particular official establishment. Development and maintenance of establishment/shift procedure plans involves worksheet completion, review, and revision (when necessary to identify clearly the establishment and shift and/or applicable ISP codes).

B. Developing Establishment/Shift Procedure Plans

Whenever FSIS issues a grant of inspection, inspection program personnel are to obtain a blank FSIS Form 5400-5 from the DO and complete it as follows:

- enter the establishment number and shift at the top of the form;
- using the ISP Guide, review each procedure listed on the form and if it applies to the establishment's operations for that shift, place an "X" in the space provided.

Inspection program personnel are to complete a separate FSIS Form 5400-5 for each shift and submit the completed form(s) to the DO.

C. Maintaining Establishment/Shift Procedure Plans

1. Deleting procedures. If an establishment has discontinued the operation(s) for which a particular procedure is performed, enter a "K" next to the "Not Performed" space on FSIS Form 5400-2 unless the establishment expects to resume the operation(s) within 4 weeks.

2. Adding procedures. If there was an error in completing FSIS Form 5400-5 or an establishment has expanded its operations (new process or product) and, as a result, the FSIS Form 5400-2 does not include procedure(s) for all establishment operation(s):

- o identify procedure(s) to be added (using the ISP Guide) on the FSIS Form 5400-5,
- o notify the DO (electronically or by mail), and
- o retain a copy of the FSIS Form 5400-5 until confirmation of the change is received.

3. Annual review. Inspection program personnel are to review the preprinted FSIS Form 5400-5 for each establishment at least annually and upon rotation to assure that there is a plan for every shift and that the plan accurately reflects the operations that the establishment currently conducts during that shift. Inspection program personnel, at least annually, or upon rotation, are to:

- o draw a line through code for any procedure that does not apply to establishment operations during that shift,
- o place an "X" in the space provided for each procedure that applies to establishment operations during that shift but is not premarked, and
- o submit completed form(s) to the DO.

X. CONDUCTING INSPECTION SYSTEM PROCEDURES

A. Multiple Establishment Duties

1. Inspection program personnel who are responsible for conducting in-plant activities in more than one establishment are to determine the order of establishment visits:

- o based on information about establishment hours of operation and compliance/noncompliance history,
- o to randomize the timing of inspection visits, and
- o when necessary, to respond to emergency situations.

2. To summarize the inspection sites for a work week, FSIS will issue an FSIS Form 5400-3B as a cover sheet for the weekly set of FSIS Forms 5400-2 when inspection program personnel are responsible for conducting in-plant activities in more than one establishment.

B. Procedure Priorities and Substitutions

1. Inspection program personnel are to review the FSIS Form 5400-2 for the establishment(s) in which they conduct in-plant activities.

2. The procedures with the highest priority number on the FSIS Form 5400-2 are the procedures with the greatest food safety significance.

3. Inspection program personnel may use professional judgment in substituting unscheduled procedures for ones specified on the FSIS Form 5400-2:

- o consistent with the Agency's food safety priorities, and
- o for the purpose of achieving FSIS's regulatory objectives.

4. Whenever inspection program personnel perform an unscheduled procedure, they are to list the ISP code on the FSIS 5400-3.

C. Performing Procedures

Inspection program personnel are to:

- o perform procedures as specified in the ISP Guide,
- o respond to identified and suspected instances of insanitary conditions, other types of adulteration, and misbranding,
- o document their findings of noncompliance with regulatory requirements,
- o advise establishment management when they find noncompliance with regulatory requirements, and
- o perform other functions, as appropriate (for example, filing directives, reviewing labels, and removing official devices).

D. Documenting Procedure Performance

1. Completing FSIS Form 5400-2 (Sample in Attachment 2)

a. The form will be utilized for documenting performance of scheduled procedures. The inspection result for a procedure will either be performed, not performed, or a noncompliance trend indicator will be circled. Only one inspection result should be entered on the schedule for each procedure.

b. The results of the procedure will either indicate compliance or noncompliance with the regulations. If the results of the procedure indicate compliance, circle the word "performed." If the results of the procedure indicate noncompliance, circle the most appropriate trend indicator.

c. All sampling procedures where FSIS inspection personnel select, process, and mail samples to the laboratory will be recorded as performed. The word "performed" should be circled on the form.

d. If the procedure is not performed, circle "not performed" on the form.

e. If the procedure is not applicable to the establishment, enter the letter "K" next to the "not performed" on the form unless the establishment expects to resume the operation(s) within 4 weeks.

f. If a procedure needs to be added, the procedure(s) to be added should be identified to the DO electronically or by mail.

g. Any questions about completing form should be directed to the PIC at the DO.

2. Completing FSIS Form 5400-3 (Sample in Attachment 2)

a. The form will be utilized for documenting performance of unscheduled procedures. The establishment number/shift and the date visited should be completed on the top of the form. The inspection result for a procedure will either be performed, not performed, or a noncompliance trend indicator will be entered. Only one inspection result should be entered on the schedule for each procedure.

b. The results of the procedure will either indicate compliance or noncompliance with the regulations. The procedure code of the procedure that is performed should be recorded and the letter of the appropriate inspection result documented in the "result code" space provided on the form. The result codes are listed at the bottom of the form. For example, if the results of the procedure indicate compliance, document the result code for the appropriate trend indicator.

c. Remember, there is no trend indicator for noncompliance with the Basic inspection procedures. Document the procedure code and leave the results code space blank. The procedure code will indicate to the DO that there is noncompliance with the Basic requirements.

d. All sampling procedures where FSIS inspection personnel select, process, and mail samples to the laboratory will be recorded as performed.

e. Any questions about completing the form should be directed to the PIC at the DO.

XI. NONCOMPLIANCE RECORDS

A. General

A Noncompliance Record and Noncompliance Record Continuation Sheet, FSIS Form 5400-4 and FSIS Form 4a, respectively, serves as FSIS's official record of noncompliance with one or more regulatory requirements. (As stated on the FSIS Form 5400-4 and 4a: "This document serves as written notification of your failure to comply with regulatory requirement(s), which could result in additional regulatory and administrative action.")

Each time performance of a procedure results in finding(s) of noncompliance with regulatory requirement(s), inspection program personnel are to complete an FSIS Form 5400-4 and, if necessary 4a, as specified in Paragraph XI.B. and using the Noncompliance Determination Guide. Inspection program personnel are to file FSIS Form 5400-4 and 4a as security items in a government office.

(For instructions on the use of FSIS Form 5400-4a when more than one inspector performs sanitation-related ISP procedures, see Appendix B to FSIS Directive 5000.1.)

1. Inspection program personnel are to provide establishment management with a copy of the FSIS Form 5400-4 and, if necessary 4a, (as soon as possible and, in any event, by the end of the tour of duty) and an opportunity to respond.

2. Until an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an FSIS Form 5400-4, the form is "open." Inspection program personnel are to review the file of "open" FSIS Form 5400-4's daily.

3. When an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an FSIS 5400-4, inspection program personnel are to file the form as "closed."

4. The IIC and appropriate inspection program personnel are to meet with establishment management weekly to discuss noncompliance findings (if any) and action(s) taken by the establishment to bring itself into compliance.

B. Completing the Form

The numbered blocks on the FSIS Form 5400-4 and 4a are to be completed as follows:

1 Date--Enter the date noncompliance occurred.

2 Record No.--Number the FSIS Form 5400-4 completed in a given establishment sequentially, by year (i.e., 1-97, 2-97, 3-97, etc., regardless of who completes the form or the shift).

3 Est. No.--Enter as a 5-digit number followed by a red meat or poultry designator and the shift number (e.g., 00345 M/2).

4 To (Name & Title)--Enter the name of the responsible establishment individual. When documenting noncompliance with the HACCP system regulations, always use the name of the official who signed the HACCP plan. When documenting noncompliance with the Sanitation SOP regulations, always use the name of the official who signed the Sanitation SOP's.

5 Personnel Notified--Enter the name of the establishment management person who was notified of the noncompliance.

6 Relevant Regulation(s)--Cite the provision(s) of the regulations with which the establishment failed to comply (e.g., § 416.14 when an establishment fails to revise its Sanitation SOP's as necessary to keep them effective and current; § 417.2(c)(1) when a HACCP plan does not list food safety hazards identified in the establishment's hazard analysis).

7 Relevant Section/Page of Establishment Procedure/Plan--Identify the relevant section or page of an establishment document when noncompliance involves failure to comply with a requirement to follow written establishment procedures (e.g., in response to a deviation from a critical limit, an establishment failed to follow the corrective action procedure(s) specified in its HACCP plan (§§ 417.2(c)(5) and 417.3(a)); an establishment failed to conduct one or more pre-operational Sanitation SOP's before the start of operations (§ 416.13(a)). If there is no applicable requirement, enter "NA".

8 Noncompliance Classification Indicators--Mark the indicator that best describes the noncompliance. (These are the same trend indicators as appear on the FSIS Form 5400-2 and -3.)

9 ISP Code--Enter the code of the procedure performed.

10 Description of Noncompliance--Describe the failure to comply with regulatory requirement(s) as fully as possible in the space provided. Include the exact location in the establishment where the noncompliance finding was made. Avoid subjective judgment terms (e.g., "dirty" or "poor"). Use the FSIS Form 5400-4a if additional space is needed to complete the description of the noncompliance.

11 Signature of Inspection Program Employee--Sign after completing blocks 1 through 10.

12 Plant Management Response--Provide establishment management with an opportunity to respond to the FSIS Form 5400-4, either verbally or in writing. Block 12 (immediate action(s)) is for action the establishment is taking to correct the noncompliance that resulted in issuance of the form, including appropriate product disposition. Block 13 (further planned action(s)) is for action the establishment plans to take to bring itself into compliance with regulatory requirements. This includes measures to prevent recurrence.

13 Signature of Plant Management and Date--If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the FSIS Form 5400-4.

14 Verification Signature of Inspection Program Employee and Date--Sign after establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of the FSIS Form 5400-4 and, if necessary 4a.

Deputy Administrator
Office of Policy, Program Development
and Evaluation

FSIS Directive 5400.5
Attachment 1

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE PLANT PROFILE (*HACCP*)	INSTRUCTIONS: All pages of this form MUST be completed. All BLOCKS must be completed or N/A indicated when not applicable.
PLANT NAME, AND PHYSICAL LOCATION ADDRESS ZIP CODE	MAILING ADDRESS (*If different*) PLANT TELEPHONE NO. (*Include Area Code*) ( ) FAX NO. (*Include Area Code*) ( )
INSPECTION SYSTEM ☐ SIS ☐ NELS ☐ NTIS	INSPECTION AUTHORITY ☐ Federal ☐ State ☐ T/A
DISTRICT NAME/NO. / CIRCUIT NAME/NO.	ESTABLISHMENT NO. (*Meat*) / ESTABLISHMENT NO. (*Poultry*)

APPROVED OPERATING HOURS

SHIFT 1 SLAUGHTER START	SHIFT 1 SLAUGHTER FINISH	SHIFT 1 PROCESSING START	SHIFT 1 PROCESSING FINISH	DAY	SHIFT 2 SLAUGHTER START	SHIFT 2 SLAUGHTER FINISH	SHIFT 2 PROCESSING START	SHIFT 2 PROCESSING FINISH
				SUNDAY				
				MONDAY				
				TUESDAY				
				WEDNESDAY				
				THURSDAY				
				FRIDAY				
				SATURDAY				

PLANT TYPE *Check applicable box(es)*

☐ Slaughter/Processing Combination ☐ Pure Processing ☐ Pure Slaughter ☐ Custom Exempt Operation ☐ Retail Exempt Operation

TOTAL PRODUCTION AREA SQ. FT. *(One total for all areas)*

ENTER THE NUMBER OF INSPECTION PROGRAM PERSONNEL WITH PBIS RESPONSIBILITIES →	SHIFT 1	SHIFT 2

Plant Management Names *(If more space is needed, use reverse)*

POSITION	SHIFT 1	SHIFT 2
President/General Manager		
Production Supervisor		
Foreman and Department		
Foreman and Department		
Foreman and Department		
Check if appropnate: ☐ HACCP/QC Manager ☐ HACCP/QC Technician ☐ Additional Foreman		

FEDERAL, STATE, LOCAL REQUIREMENTS *(Certificates, Letters, Permits, Etc.)*

ITEM	CERTIFICATE DUE DATE	CURRENT CERTIFICATE ON FILE YES (✓)	DATE	N/A (✓)
Potable Water Source ☐ Municipal				
Potable Water Source ☐ Wells				
Shipping Inedible Material *(If applicable)*				
Ice Potability *(Outside supplied)*				
Other *(Specify)*:				
Sewage *Check Date* →				
Backflow *Check Date* →				

List Government Office Facilities and Services *(Location, security file, restroom/locker, laundry facilities, Electronic coded entry, etc.)*

SPECIAL TELEPHONE CODES *(Include Area Codes)*	FSIS DESIGNATED PARKING SLOT: *(If yes, give location and/or slot number)* ☐ Yes ☐ No

PRODUCT AND OPERATIONS PROFILE *(HACCP)*

PRODUCT PROCESS ACTIVITIES AT THIS PLANT (Place an "X" in all appropriate blocks)

I

- ☐ Boning/Grinding
- ☐ Boneless Meat Reinspection
- ☐ Breaking/Cutting
- ☐ Chipping/Dicing
- ☐ Crackling/Skin popping
- ☐ Denaturing/Tanking
- ☐ Freezing
- ☐ Ice glazing parts
- ☐ Labeling/Packaging only
- ☐ Raw meat/poultry patties (without extenders)
- ☐ Poultry cut-up (RTC)
- ☐ Portion control
- ☐ Rendering/refining (edible animal fats, margarine, lard)
- ☐ Rendering (inedible)
- ☐ Basting
- ☐ Exports
- ☐ Tenderizing (mechanical other than massaging)

II

- ☐ Batter/breading
- ☐ Veal and Calf Skinning
- ☐ Freeze drying
- ☐ Injecting
- ☐ Marinating
- ☐ Meat and/or poultry patties (with extenders and other ingredients)
- ☐ Pumping
- ☐ Tenderizing (with solutions, massaging)
- ☐ Filtered lard
- ☐ Fresh sausage
- ☐ Margarine
- ☐ Assembly of products only
- ☐ Casings
- ☐ Slicing
- ☐ Smoking for appearance and flavor only (no formulation)
- ☐ Acidified products

III

- ☐ Curing
- ☐ Pizza
- ☐ Dough covered/ wrapped product
- ☐ Mechanical deboning
- ☐ Pizza topping
- ☐ Canned (perishable)
- ☐ Corn dogs
- ☐ Cured beef or pork (corned beef)
- ☐ Cured sausage
- ☐ Cured, water added pork products
- ☐ Fried chicken
- ☐ Cooked meat/poultry without formulation (open kettle, charbroil, braise)
- ☐ Sandwiches (meat brought from outside plant)
- ☐ Canning (thermally processed /shelf stable)
- ☐ Cooked and/or smoked sausages
- ☐ Dinners/entrees

IV

- ☐ Dry/Semi-dried sausage
- ☐ Imports
- ☐ Meat/poultry pies
- ☐ Certification (freezing, heating, drying)
- ☐ Jerky * Cooked meat/poultry
- ☐ Formulation (frying, barbequing, etc.)
- ☐ Rolls/loaves/ luncheon meats
- ☐ Jellied products
- ☐ Cooked and/or smoked pork products
- ☐ Soups/salads/gravy
- ☐ Cooked patties (all)
- ☐ Cooked meats (roast beef, corned beef)
- ☐ Partially defatted (species) fatty tissues

PLEASE ADD ANY PRODUCTS/PROCESSES NOT GIVEN ABOVE

PARTIAL QUALITY CONTROL PROGRAMS/PROCEDURES

LIST BY NAME ALL PARTIAL QUALITY CONTROL PROGRAM(S) AND PROCEDURE(S) *(If more space is needed, use a separate sheet)*

LIST PLANT'S SPECIAL RULES *(i.e., hair nets, loose items in shirt coat pockets) (If more space is needed, use reverse)*

FSIS Directive 5400.5
Attachment 1

DATA FOR THE COMMON ON-LINE REFERENCE FOR ESTABLISHMENTS *(HACCP)*	EST. NO *(Meat)*	EST. NO. *(POULTRY)*	EST. NO. *(Equine)*	EST. NO. *(OTHER)*
Instructions: Place an "X" in the blocks appropriate for each plant. Make your decisions based on your knowledge of authorized activities for each plant and your observations of activities conducted at each plant.				
	MEAT	POULTRY	EQUINE	OTHER
SLAUGHTER DATA	☐ Cattle ☐ Calves ☐ Sheep ☐ Swine ☐ Reindeer (v) ☐ Buffalo (v)	☐ Young Chick ☐ Mature chick ☐ Turkeys ☐ Geese ☐ Ducks ☐ Guineas ☐ Rabbit (v) ☐ Ratite (v) ☐ Quail (v)	☐ Equine	
PROCESSING DATA	☐ Raw product - Ground ☐ Raw - Not Ground ☐ Thermally Processed/Commercially Sterile ☐ Not Heat Treated - Shelf Stable ☐ Heat Treated - Shelf Stable ☐ Fully Cooked - Not Shelf Stable ☐ Heat Treated But Not Fully Cooked - Not Shelf Stable ☐ Product With Secondary Inhibitors - Not Shelf Stable			

* ID SERVICE CODE TABLE
N = No ID Service
1 = Plant handling unwrapped meat
2 = Plant that can handle wrapped or boned meat products only
3 = Combination of 1 and 5
4 = Combination of 2 and 5
5 = Approved identification services

OTHER DATA	MEAT	POULTRY	EQUINE	OTHER
ID Service *(enter code)* * Food Inspection Service Certification Service Voluntary Poultry Inspection Voluntary Equine Processing Animal Food Inspection Voluntary Processing	☐ ____ ☐ ☐	☐ ____ ☐ ☐	☐ ____ ☐ ☐	☐ ____ ☐ ☐ ☐
	☐ Beef ☐ Veal ☐ Lamb ☐ Goat ☐ Pork ☐ Buffalo ☐ Reindeer	☐ Poultry ☐ Rabbit ☐ Ratites ☐ Quail		

PLANT INFORMATION *(The entries below pertain to the plan as a whole.)*

EXEMPTED ACTIVITIES		OTHER INDICATORS		
☐ Custom Slaughter ☐ Custom Processing ☐ Retail ☐ Buddhist ☐ Other *(specify)*: _____	☐ Confuscian ☐ Islamic ☐ Kosher	☐ Other FDA ☐ HQ Point ☐ Tissues/Organs for Research/ Pharmaceuticals	☐ Inedible Fats ☐ Inedible Fat Shipper ☐ Railsiding ☐ Unborn Fetal Blood	☐ Inedible Blood ☐ Edible Blood ☐ High Pathology ☐ High Antibiotic Residue

PAGES 1, 2 AND 3 MUST BE COMPLETED, BEFORE SIGNING.

SIGNATURE OF FSIS INSPECTOR-IN-CHARGE PREPARING FORM | DATE

FSIS FORM 5400-1.3 (9/97) INSPECTOR-IN-CHARGE PAGE 3 OF 3

FSIS Directive 5400.5
Attachment 1

FSIS Form 5400-1, Plant Profile

General Instructions

FSIS Form 5400-1, Plant Profile, should be completed as each establishment becomes subject to the HACCP provisions of the Pathogen Reduction/HACCP regulation (see Directive 5400.5, III).
All pages of the form are to be maintained as a set.
The form is to be completed in duplicate by the inspector-in-charge.
The original copy of the form is filed in the government office where it is accessible to all inspection program personnel. If available, the previous plant profile (FSIS Form 8810-1) should be attached to the new original. The copy of the revised plant profile (FSIS Form 5400-1) should be mailed to the district office.
All sections must be completed or an "NA" placed in the space provided.
Any additional information should be recorded on a separate sheet, referenced in the appropriate space on the form, and the sheet attached to the form.

Plant Profile
Note: The numbers in these instructions correspond to the circled numbers on the Form.

1. Plant Name and physical location.
Enter the plant name and location. Give a brief description of the location , e.g., street address, zip code, local geographic location, route number or highway, etc.

2. If the mailing address is different from the location or street address include mailing address.

3. Enter the plant phone number, including area code.

4. Enter the plant FAX number, including area code.

5. Inspection Activities
Mark any applicable space.

6. Inspection Authority.
Mark the appropriate box .

7. District Name/No.
Identify the district by name or abbreviation and enter the numerical designation for that district.

8. Circuit Name/No.

Identify the circuit by name and number, e.g. Portland/09, etc.
Circuit names and numbers are found in the MPI Directory.

9. Establishment Number.
Enter the establishment number in PBIS format, e.g. 00038--P or 00038--M. If the establishment produces both meat and poultry enter both numbers.

10. Approved Operating Hours.
Enter the hours of operation approved by the district manager. If slaughter and processing have different hours enter in the appropriate space. If the plant has more than one shift use the space for second shift. Use military time when entering hours of operation.

11. Plant type.
Mark all boxes that are appropriate to the plant's operations.

12. Total Production Area(s) Sq. Ft.
Enter the total plant production area in this space. Enter the area in square feet. This information can be found on blueprints. Enter only the square footage for area where inspection program responsibilities exist.

13. Enter the number of inspection program personnel with PBIS responsibilities.

14. Plant Management Names.
Enter the name(s) of individuals in plant management and their titles. Write in the appropriate titles if they differ from those on the form. The names listed should be those with which inspection program personnel interact with on a routine basis regarding regulatory requirements. The HACCP/QC spaces should be marked if they are applicable.

15. Federal, State, or Local Requirements.
Required certificates, permits, letters, etc. can vary across the country. Determine if the item is required in the establishment. If so, check the file and determine the date listed on the current record. Record this date. Based on the requirement for renewal, enter the due date in pencil. If additional certificates or permits are on file, enter these on the back of the form.

16. List Government office, facilities, and services.
Enter information in this space that will assist inspection program personnel entering the establishment in locating facilities such as rest rooms, locker rooms, security files, etc.

17. Special telephone codes.
Enter the codes necessary to operate the telephone and reach various departments within the establishment. Enter the number for the circuit supervisor and the district office. Do not enter credit card numbers. Also, indicate location of FSIS dedicated line for a computer hook up.

18. FSIS Designated parking spot. Mark the appropriate space and indicate the slot number if applicable.

Page Two

19. Products and Operations.
Mark all spaces of applicable products and operations conducted in the establishment. Add any products not listed.

20. Partial Quality Control Programs or Procedures (PQCP).
List each QC program or procedure by name.

21. Plants Special Rules.
List any special rules in place in the plant that effect inspection program personnel in their regulatory capacity. Required hair nets, special foot dips, prohibition on loose items in pockets, etc. If additional room is needed use the reverse side of the form.

Page Three

22. Establishment Number.
Enter all appropriate establishment numbers in five digit PBIS format.

23. Slaughter Data
Place a mark in the boxes beside those species slaughtered at the establishment.

24. Process Data
Place a mark in all applicable boxes. These eight processes are representative of the HACCP process designations (417.2 (b)(1)). Slaughter is covered under 24.

25. Other Data
Place a mark in all applicable spaces. Enter the identification service (ID) code from the table above the space.

26. Voluntary Processing
Place a mark in the spaces beside those species processed at the establishment.

27. Exempted Activities
Place a mark in the applicable spaces.

28. Other Indicators
Place a mark in the applicable spaces.

29. Signature and Date
After completing the form, the inspector-in-charge will sign and date the form.

FSIS Directive 5400.5
Attachment 2
Procedure Schedule

Establishment/Shift: 00038 M/1 Page ID: 19 Scheduled Date: 01/27/98
Operating Hours: 0630-1500 Visited Date:

Sanitation /Procedure Verification 01A02 Determ Est has met reg req'ments for devlpment and maintenance of sanitation SOP Pri: 8 Pg: 1-2 Rate:	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
Sanitation/Operational Sanitation 01C01 Verify Est SSOP recds ensur monit effect op; corr action init'd to prev contm Pri: 8 Pg: 1-4 Rate: 260	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
HACCP/Raw Ground 03B01 Rev HACCP sys inclu recds; obs cndts; ck 2 or more proc steps include Pri: 8 Pg: 3-1 Rate: 52	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
HACCP/Raw Not Ground 03C02 Ver HACCP recds ensure effective mult CCPs limits, corr act, ver at proc steps Pri: 8 Pg: 3-6 Rate:156	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
Economic/Wholesomeness/Products 04A03 verify recds; conduct hands-on to deter MSS/MSP/PDBFT/PDPFT/etc meets reg stnd Pri: 7 Pg: 4-3 Rate: 52	a) Performed b) Not Performed g) Economic h) Misbranding i) Protocol
Sampling/Residue 05C01 Rndm select sample(s) for residue/diag determination Pri: 5 Pg: 5-3 Rate: 13	a) Performed b) Not Performed
Other Inspection Requirements/Facilities and Equipment Standard 06D01 Verify recds; conduct hands-on to deter random fac/equip meets requirements Pri: 5 Pg: 6-2 Rate: 13	a) Performed b) Not Performed j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-2 (9/97) 10/01/97

FSIS Directive 5400.5
Attachment 2

Procedure Schedule

Establishment/Shift: 00038 M/1 Page ID: 19 Scheduled Date: 01/27/98

Operating Hours: 0630-1500 Visited Date:

Sanitation /Procedure Verification 01A02 Determ Est has met reg req'ments for devlpment and maintenance of sanitation SOP Pri: 8 Pg: 1-2 Rate:	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
Sanitation/Operational Sanitation 01C01 Verify Est SSOP recds ensur monit effect op; corr action init'd to prev contm Pri: 8 Pg: 1-4 Rate: 260	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation
HACCP/Raw Ground 03B01 Rev HACCP sys inclu recds; obs cndts; ck 2 or more proc steps include Pri: 8 Pg: 3-1 Rate: 52	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
HACCP/Raw Not Ground 03C02 Ver HACCP recds ensure effective mult CCPs limits, corr act, ver at proc steps Pri: 8 Pg: 3-6 Rate: 156	a) Performed b) Not Performed c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification
Economic/Wholesomeness/Products 04A03 verify recds; conduct hands-on to deter MSS/MSP/PDBFT/PDPFT/etc meets reg stnd Pri: 7 Pg: 4-3 Rate: 52	a) Performed b) Not Performed g) Economic h) Misbranding i) Protocol
Sampling/Residue 05C01 Rndm select sample(s) for residue/diag determination Pri: 5 Pg: 5-3 Rate: 13	a) Performed b) Not Performed
Other Inspection Requirements/Facilities and Equipment Standard 06D01 Verify recds; conduct hands-on to deter random fac/equip meets requirements Pri: 5 Pg: 6-2 Rate: 13	a) Performed b) Not Performed j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-2 (9/97) 10/01/97

FSIS Directive 5400.5
Attachment 2

Procedure Schedule

Establishment/Shift: Visited Date:

Procedure	Pri	Page	Procedure Description	Result Code (Enter A thru P as defined below)

Result Codes

a) Performed	Non-Compliance Indicators				
	(SSOP)	(HACCP)	(Economic/ Wholesomeness)	(E-Coli)	(Other Inspection Requirements)
	c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation	c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification	g) Economic h) Misbranding i) Protocol	m) Basic n) Other	j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-3 (9/97)

FSIS Directive 5400.5
Attachment 2
Procedure Schedule

Establishment/Shift: 00038 M/1 Visited Date: 1/27/97

Procedure	Pri	Page	Procedure Description	Result Code (Enter A thru P as defined below)
03A01				a
03A01				a
03J01				c
03J02				a

Result Codes

a) Performed	Non-Compliance Indicators				
	(SSOP)	(HACCP)	(Economic/ Wholesomeness)	(E-Coli)	(Other Inspection Requirements)
	c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation	c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification	g) Economic h) Misbranding i) Protocol	m) Basic n) Other	j) Lighting k) Structural l) Outside Premises p) Product Based

FSIS Form 5400-3 (9/97)

FSIS Directive 5400.5
Attachment 2
Establishment Schedule Summary

mm/dd/yy Sunday	mm/dd/yy Monday	mm/dd/yy Tuesday	mm/dd/yy Wednesday	mm/dd/yy Thursday	mm/dd/yy Friday	mm/dd/yy Saturday

Note: * Indicates a Preoperational Sanitation Procedures. Establishments are listed in Numeric order and Travel Times may vary.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

FSIS Directive 5400.5
Attachment 3

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD	1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.

4. TO (*Name and Title*)

5. PERSONNEL NOTIFIED

6. RELEVANT REGULATION(S)

7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN → | HACCP | SOP | OTHER

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS					
	A. ☐ SSOP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ Product		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ Facility		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

10. DESCRIPTION OF NONCOMPLIANCE:

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (*immediate action(s)*):

13. Plant Management Response (*further planned action(s)*):

This document serves as written notification that your failure to comply with regulatory requirement(s), which could result in additional regulatory and administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

FSIS FORM 5400-4 (9/97) INSPECTOR COPY

NONCOMPLIANCE CLASSIFICATION INDICATORS GUIDE

ACTIVITY	ELEMENT	INDICATOR
Sanitation	Pre-operational Operational	Corrective Action, Records, Monitoring, Implementation
	Procedure Review	Basic—results are reported by procedure
HACCP	Hazard Analysis/Plan/Validation/ Recordkeeping/Reassessment—Basic	Basic—results are reported by procedure
HACCP—Elements B-J	Observation Records Review	Corrective Action; Recordkeeeping; Verification; Monitoring
Microbiological Testing - FSIS	Directed Sampling- e.g., Listeria, Salmonella, E. Coli	Performed
Microbiological Testing - Establishment	E. Coli Written specimen Absence of Testing Recording Test results	Basic-results are reported by procedure
	Sample Collection Sample Analysis Records of Test	Other
Sampling	Salmonella Economic Directed Residue	No Indicator-results reported as performed
		No Indicator-results reported by procedure
Other Inspection Requirements	Export	Misbranding or No Indicator—results reported by procedure
	Custom Exempt/Retail	No Indicator—results reported by procedure
	Facilities and Equipment Condemned and Inedible Sewage Water Pest and Rodent Control	Lighting Structural Outside Premises Product Based
Economic/Wholesomeness	% Yield/Shrink X% Solution MSS/MSP/PDBFT/PDPFT/etc. Batter/Breading Product Standards CN/Grade Labeling/etc. Net Weight General Labeling Finished Product Standards/AQL/Boneless Meat, etc.	Economic Misbranding Protocol

FSIS Directive 5400.5
Attachment 3

☐ Attachment

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD CONTINUATION SHEET**	1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (*Name and Title*)			
5. PERSONNEL NOTIFIED			
6. RELEVANT REGULATION(S)			
7. RELEVANT SECTION/PAGE OF ESTABLISHMENT PROCEDURE/PLAN ➜	| HACCP	| SOP	| OTHER
8. ISP CODE	9. NONCOMPLIANCE INDICATOR		
10. DESCRIPTION OF NONCOMPLIANCE :			

SAMPLE COPY

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	12. DATE

FSIS FORM 5400-4a (9/97) **ORIGINAL - Establishment**

FSIS Directive 5400.5
Attachment 4

ESTABLISHMENT/SHIFT INSPECTION PROCEDURE WORKSHEET
HACCP Est./Shift

ESTABLISHMENT/SHIFT INSPECTION PROCEDURE WORKSHEET
HACCP Est./Shift

Procedures				
01A01 [ ]	04B01 [ ]			
01B01 [ ] 02 [ ]	02 [ ] 03 [ ] 04 [ ]			
01C01 [ ] 02 [ ]	04C01 [ ]			
03A01 [ ]	05A01 [ ] 02 [ ] 03 [ ]			
03B01 [ ] 02 [ ]	05B01 [ ] 02 [ ]			
03C01 [ ] 02 [ ]	05C01 [ ]			
	06A01 [ ]			
03D01 [ ] 02 [ ]	06B01 [ ]			
03E01 [ ] 02 [ ]	06C01 [ ]			
	06D01 [ ] 02 [ ] 03 [ ]			
03F01 [ ] 02 [ ]				
03G01 [ ] 02 [ ]	06E01 [ ]			
	06F01 [ ] 02 [ ]			
03H01 [ ] 02 [ ]	06G01 [ ]			
	07A01[ ]			
03I01 [ ] 02 [ ]				
03J01 [ ] 02 [ ]				
04A01 [ ] 02 [ ] 03 [ ] 04 [ ]				

FSIS FORM 5400-5 (9/97) USDA-FSIS

FSIS Directive 5400.5
Attachment 5

Noncompliance Determination Guide

The Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule amended FSIS's regulations to require establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur. These regulations are the framework for a modernized approach to inspection. FSIS expects to review and amend its other food safety and consumer protection regulations (including rules to prevent misbranding and economic adulteration) for consistency with this framework and to improve their usefulness to Agency personnel and the public.

The purpose of a HACCP system is to control food safety hazards that are reasonably likely to occur in the food production process. Among other things, an establishment's HACCP plan must include critical limits designed to ensure that performance standards and other process or product requirements in FSIS's regulations are met.

For inspection program activities in establishments that are subject to the HACCP system regulations, FSIS is replacing the Deficiency Classification Guide and the Process Deficiency Record with the Noncompliance Determination Guide (NDG) and the Noncompliance Record (NR). Inspection program personnel are to apply the NDG in all regulatory areas.

Outcomes and Trends

Whenever inspection program personnel perform a procedure in the Inspection System Procedure (ISP) Guide (whether scheduled or unscheduled), they either do or do not find noncompliance with one or more regulatory requirements. When noncompliance with regulatory requirements is not found, the procedure is recorded as "performed" on the Procedure Schedule (PS) (see FSIS Directive 5400.5, Paragraph X.). (No other entry or record is required. FSIS sampling is recorded as "performed" as well.)

FSIS Directive 5400.5
Attachment 5

Inspection program personnel who find noncompliance with one or more regulatory requirements also (1) categorize the noncompliance, by marking the appropriate PS and NR indicator, and (2) using an NR, document and follow-up on their findings. (See FSIS Directive 5400.5, Paragraph XI., for information about the NR.)

The purpose of trend indicators is to improve the Agency's ability to evaluate establishment performance and process control by providing information on trends in noncompliance. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance. Inspection program personnel are to mark the indicator that best describes the noncompliance.

The following summary describes the indicators for various PBIS activities.

Plant Process

For the regulations on Sanitation SOP's (SSOP's), there are four indicators: monitoring, corrective action, recordkeeping, and implementation. The first three indicators correspond to specific requirements in part 416 (see also FSIS Directive 5000.1, Part Three, Paragraph III.B.); inspection program personnel who find that an establishment's noncompliance with requirements for SSOP implementation involves failures in more than one of these areas should use the fourth indicator.

For the regulations on HACCP systems, there are four indicators: monitoring, corrective action, recordkeeping, and verification. Each corresponds to specific requirements in part 417 (see also FSIS Directive 5000.1, Part Two, Paragraph III.B.).

For these regulations and the regulations on E. coli testing and criteria, there also is an indicator for basic noncompliance findings (see below and FSIS Directive 5000.1, Paragraph II. of Parts Two, Three, and Four).

For other product regulations addressed by an 04 Activity or an 06A Export element, there are three indicators: economic, misbranding, and protocol.

> Inspection program personnel who find noncompliance when performing an Other Requirements procedure in an 04 Element prior to the labeling or branding of a product should use the economic indicator. This is the only appropriate indicator when performing an 04C procedure. (Examples: the number of noncomformances found when performing a finished product standards test exceed the regulatory limit; the scale used to determine a product's net weight is found to be inaccurate.)

Inspection program personnel who find noncompliance when performing an Other Requirements procedure in an 04 or 06 Element after product is labeled, branded, or packaged should use the misbranding indicator. This is the appropriate indicator for noncompliance with net weight or standard of identity or composition requirements.

If an establishment that has elected to use an alternative production method or process has on file a protocol which was reviewed by FSIS personnel, inspection program personnel who find economic adulteration or misbranding when performing an Other Requirements procedure in an 04 Element should use the protocol indicator. (Do not use this indicator for deviations from a QC program that is not a regulatory requirement. When a deviation from a plant's QC program is also a failure to met a regulatory requirement, that regulatory failure will be documented using the most appropriate trend indicator. The documentation on the NR's should be as complete as possible.)

For facility regulations, there are four indicators: lighting, structural, outside premises, and product-based. Inspection program personnel who find noncompliance when performing procedures in an 06D, 06E, or 06F Element should select among these indicators based on the root cause of the noncompliance. (For example, noncompliance resulting from a slaughter flooring problem should be classified as structural; noncompliance due to leaking pipes on the loading dock should be classified as outside premises.)

Inspection program personnel who find instances of indirect product contamination potential when performing an ISP procedure for part 416 (SSOP's), may use the fourth facilities trend (product-based) indicator. (For example, inspection program personnel performing an SSOP procedure to verify the cleaning and sanitizing of a hide-puller, find that the equipment is clean and sanitary and will not cause direct product contamination. However, on a nearby wall, there is material which could cause indirect product contamination. This is not an SSOP noncompliance, but would be a facilities noncompliance and recorded using the product-based indicator.

Food Safety Noncompliance

FSIS Directive 5000.1 provides instructions for enforcing the regulations on HACCP systems and SSOP's. It also addresses actions based on noncompliance with the E. coli process control verification requirements and the pathogen reduction performance standards for Salmonella. FSIS Directive 5000.1 divides possible failures to comply with food safety-related regulations into two categories: basic

compliance/noncompliance and compliance/noncompliance with other requirements.

Basic Compliance/Noncompliance

Basic compliance checks (ISP procedures 01A01, 03A01, and 05A01) focus on whether an establishment has failed to institute the systems required by FSIS regulations: Either the establishment does not have a required plan or procedures or recordkeeping at all (for example, when an establishment does not have written SSOP's or written procedures for collecting samples for E. coli testing), or what the establishment has clearly does not meet regulatory requirements (for example, when an establishment's SSOP's do not identify which procedures are pre-operational procedures, or when a HACCP plan does not list the critical limits to be met at each critical control point or does not identify the corrective action to be followed in response to a deviation from a critical limit at a critical control point).

Compliance/Noncompliance--Other Requirements

This category includes failure to comply with any requirement not addressed by a basic compliance check. As instructed in FSIS Directive 5000.1, there are situations in which finding noncompliance with these requirements supports an inspection program employee initiating the withholding of inspection (see, in particular, Paragraph III.C. of Parts Two and Three). In other cases, FSIS will use documentation of recurring or repeated noncompliance in determining what further action to take.

In addition, inspection program personnel who, as a result of performing ISP procedure 03B01, 03C01, 03D01, 03E01, 03F01, 03G01, 03H01, 03I01, or 03J01, determine that an establishment has failed to comply with one or more regulatory requirements are to perform the corresponding ISP procedure (03B02, 03C02, 03D02, 03E02, 03F02, 03G02, 03H02, 03I02, or 03J02) for the same lot of product (see FSIS Directive 5000.1).

Other Consumer Protection Noncompliance

For all remaining Activities, Elements, and Procedures, inspection program personnel are to document noncompliance on an NR and, as appropriate, continue to apply a "U.S. Retained/Rejected" tag to misbranded or economically adulterated product. When a "U.S. Retained/Rejected" tag is not used (for example, when a roll of labels stored on a pallet has features that are not of the prominence required by regulation), inspection program personnel are to select the appropriate trend indicator (economic in the preceding example).

When, as a result of performing one of these procedures, inspection program personnel find noncompliance with one or more food safety requirements, they should use the appropriate food safety procedure in documenting the noncompliance.

Inspection program personnel who suspect misbranding or economic adulteration are to take action (such as tagging) to control suspect product.

Attachment 6

INSPECTION SYSTEM PROCEDURE GUIDE

Internal Code Legend:
01#: Activity
Capital Letter: Element
Two Digit Number: Procedure

Ex. 01A01

01A Basic SSOP Compliance Checks

01A01	Written SSOP's describe procedures the establishment conducts daily to prevent direct contamination or adulteration of product. Pre-operational procedures are identified. Pre-operational procedures address the cleaning of food contact surfaces of facilities, equipment, and utensils. The frequency SSOP is specified for each procedure. The employee(s) responsible for implementing and maintaining the procedures are identified. Identified records, on a daily basis, document implementation and monitoring of SSOP's and any corrective actions taken. The individual with overall authority on-site, or a higher level official, signed and dated the SSOP's upon initial implementation and any modification.	Part 416 FSIS Dirs. 5000.1 Part 3, Par. II	As appropriate, review Sanitation SOP's and recordkeeping. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

01B Other Sanitation

01B01	**Pre-Operational** The establishment--conducts pre-operational procedures before beginning operations, and monitors daily implementation procedures. Pre-operational procedures are sufficient to prevent direct contamination or adulteration of product(s). When SSOP's--or procedures specified therein--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration. The establishment--routinely evaluates the effectiveness of SSOP procedures, and revises procedures when necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. Daily records document--implementation of pre-operational procedures, and monitoring of pre-operational procedures; corrective actions taken (if any). Records are initialed and dated by employee identified in SSOP's as responsible for	308.8 312.6 381.57 381.58 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III	Review written pre-operational procedures in SSOP's and related records. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").

01B Other Sanitation

01B01	implementing and monitoring specified procedure(s). The establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any). Part 416-required records are--retained for at least 6 months; on-site for at least 48 hours, and available within 24 hours of request if stored off-site.	308.8 312.6 381.57 381.58 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III

01B Other Sanitation

01B02	**Pre-Operational** The establishment--conducts pre-operational procedures before beginning operations, and monitors daily implementation procedures. Pre-operational procedures are sufficient to prevent direct contamination or adulteration of product(s). When SSOP's--or procedures specified therein--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration. Daily records document--implementation of pre-operational procedures, and monitoring of pre-operational procedures; corrective actions taken (if any).	308.8 312.6 381.57 381.58 381.99 Part 416 FSIS Dir. 5000.1 Part Three, Par. III	(1) Review written pre-operational procedures in SSOP's and (if available) related records. (2) Observe conduct of pre-operational procedures in SSOP's. (3) Observe and/or test sanitary conditions (use method in Appendix A in slaughter operations and check one or more areas/departments in other operations). Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment rooms or compartments as "U.S. Rejected").

01C Other Sanitation

01C01	**Operational** The establishment--conducts procedures during operations at frequencies specified in SSOP's, and monitors daily implementation of procedures conducted during operations. Procedures conduced during operations are sufficient to or adulteration of product(s). When SSOP's--or procedures specified therein--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration. The establishment--routinely evaluates the effectiveness of SSOP procedures, and revises procedures when necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. Daily records document--implementation of operational procedures, and monitoring of operational procedures; corrective actions taken (if any).	308.3 308.8 312.6 318.17(j)(3) 381.57 381.61 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III	Review written procedures in SSOP's that are conducted during establishment operations and related records. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").

01C Other Sanitation

01C01	Records are initialed and dated by employee identified in SSOP's as responsible for implementing and monitoring specified procedure(s). The establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any). Part 416-required records are– retained for at least 6 months; on-site for at least 48 hours, and available within 24 hours of request if stored off-site.	308.3 308.8 312.6 318.17(j)(3) 381.61 381.57 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III

01C Other Sanitation

01C02	**Operational** The establishment--conducts procedures during operations at frequencies specified in the SSOP's, and monitors daily implementation of procedures conducted during operations. Procedures conducted during operations are sufficient to prevent direct contamination or adulteration of product(s). When SSOP's--or procedures specified therein--failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration. Daily records document--implementation procedures, conducted during operations and monitoring of procedures conducted during operations; corrective actions taken (if any).	308.3 308.8 312.6 318.17(j)(3) 381.61 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III	(1) Review written procedures in SSOP's that are conducted during establishment operations and (if available) related records. (2) Observe conduct of procedures in SSOP's and corrective action(s) during establishment operations. (3) Observe and/or test sanitary conditions (check one or more areas/departments). Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").

01C Other Sanitation

01C02	Daily records are maintained which document the implementation and monitoring of operational activities, as well as initiation of corrective actions. The records are authenticated by the date and initials of responsible establishment employee.	308.3 308.8 312.6 318.17(j)(3) 381.61 381.99 Part 416 FSIS Dir. 11,100.3

02
Reserved

03A01 HACCP Basic Compliance Checks

03A01	The establishment has conducted a hazard analysis. The hazard analysis includes food safety hazards reasonably likely to occur, a flow chart, and identifies intended use or consumers of the finished product(s). If one or more food safety hazards are reasonably likely to occur, establishment has a written HACCP plan for each product (process). The establishment has conducted validation activities, and records include multiple results that verify monitoring of CCP's and conformance with critical limits, and after each deviation from a critical limit (if any), subsequent results support adequacy of corrective action(s) in achieving control. The establishment reassesses the hazard analysis–if, after hazard analysis revealed no food safety hazards reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists. Before producing a new product for distribution, the establishment has conducted hazard analysis and has an applicable HACCP plan. If in distribution for more than 90 days, HACCP plan has been validated. If the HACCP plan covers more than one product, all products are within one of nine specified	Part 417 § 304.3(c) or § 318.22(c) Directive 5000.1 Part 3, Par. II	When regulations first apply and as appropriate thereafter, review hazard analysis, HACCP plan(s), and recordkeeping. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03A01 HACCP Basic Compliance Checks

03A0I	processing categories. The HACCP plan(s): lists food safety hazard(s) identified in hazard analysis (exception: thermally processed/ commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X); lists CCP's for each food safety hazard; lists critical limits to be met at each CCP; lists procedures to be used to monitor each CCP and frequency with which performed; identifies corrective actions to be followed in response to a deviation from a critical limit at a critical control point; lists verification procedures and frequency with which performed. The recordkeeping system documents monitoring of CCP's and includes records with actual values and observations. The responsible establishment official signed and dated the HACCP plan upon initial acceptance, and at least annually thereafter. If the HACCP plan modified, responsible establishment official signed and dated.	Part 417 § 304.3(c) or § 381.22(c) Directive 5000.1 Part 3, Par. II

03B Raw Product--Ground

03B01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment perform a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring and verification (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits), and/or Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03B Raw Product--Ground

03B01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plant; if HACCP plan reassessment revealed that a HACCP plan no longer meets § 417.2(c) requirements the establishment modified the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with the selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. The establishment has implemented controls to ensure data integrity for plan records	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03B Raw Product--Ground

03B01	maintained on computers (if any). 417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are available within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03B RawProduct–Ground

03B02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. The establishment reassessed the	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan. Establishment personnel perform tasks specified in plan, take corrective actions, and review production records as documented in its records. The HACCP plan in operation prevents the distribution of adulterated product. (1) Observe monitoring and verification activities and review results for a given shipment of product. (2) Review records for a given shipment of product. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action

03B Raw Product--Ground

03B02	plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan reassessment or modification meets the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	consistent with applicable directive(s).

03C Raw Not Ground

03C01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits). Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03C Raw Not Ground

03C01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with the selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. The establishment has implemented controls to ensure data integrity for plan records maintained on computers.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03C Raw Not Ground

03C01	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03C Raw Not Ground

03C02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. The establishment reassessed the	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan. Establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records. The HACCP plan in operation prevents the distribution of adulterated product? (1) Observe monitoring and verification activities and review, results for a given shipment of product. (2) Review records for a given shipment of product.

03C Raw Not Ground

03C02	HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. The establishment has implemented controls to ensure data integrity for plan records maintained on computers. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03D Thermally Processed/Commercially Sterile

03D01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment–performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits). Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03D Thermally Processed/Commercially Sterile

03D01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with the selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. The establishment has implemented controls to ensure data integrity for plan records	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03D Thermally Processed/Commercially Sterile

03D01	maintained on computers. 417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03D Thermally Processed/Commercially Sterile

03D02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. The establishment reassessed the	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product? (1) Observe monitoring and verification activities and review, results for a given shipment of product. (2) Review records for a given shipment of product. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03D Thermally Processed/Commercially Sterile

03D02	HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03E Not Heat Treated-Shelf Stable

03E01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits). Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03E Not Heat Treated-Shelf Stable

03E01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03E Not Heat Treated-Shelf Stable

03E01	The establishment has implemented controls to ensure data integrity for plan records maintained on computers. 417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03E Not Heat Treated-Shelf Stable

03E02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product. (1) Observe monitoring and verification activities and review, results for a given shipment of product. (2) Review records for a given shipment of product. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03E Not Heat Treated-Shelf Stable

03E02	The establishment reassessed the HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03F Heat Treated-Shelf Stable

03F01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits). Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03F Heat Treated-Shelf Stable

03F01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03F Heat Treated-Shelf Stable

03F01	The establishment has implemented controls to ensure data integrity for plan records maintained on computers. 417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03F Heat Treated-Shelf Stable

03F02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product. (1) Observe monitoring and verification activities and review, results for a given shipment of product. (2) Review records for a given shipment of product. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03F Heat Treated-Shelf Stable

03F02	The establishment reassessed the HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03G Fully Cooked-Not Shelf Stable

03G01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits). Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03G Fully Cooked-Not Shelf Stable

03G01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. The establishment has implemented controls to ensure data integrity for plan records maintained on computers.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03G Fully Cooked-Not Shelf Stable

03G01	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03G Fully Cooked-Not Shelf Stable

03G02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. The establishment reassessed the	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product. (1) Observe monitoring and verification activities and review, results for a given shipment of product. (2) Review records for a given shipment of product. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03G Fully Cooked-Not Shelf Stable

03G02	HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03H Heat Treated But Not Fully Cooked-Not Shelf Stable

03H01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment–performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits). Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03H Heat Treated But Not Fully Cooked-Not Shelf Stable

03H01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. The establishment has implemented controls to ensure data integrity for plan records maintained on computers.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03H Heat Treated But Not Fully Cooked-Not Shelf Stable

03H01	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03H Heat Treated But Not Fully Cooked-Not Shelf Stable

03H02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. The establishment reassessed the	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product. (1) Observe monitoring and verification activities and review, results for a given shipment of product. (2) Review records for a given shipment of product. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03H Heat Treated But Not Fully Cooked-Not Shelf Stable

03H02	HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03I Product with Secondary Inhibitors-Not Shelf Stable

03I01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment–performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits). Review and correlate records with random observation of establishment activities. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03I Product With Secondary Inhibitors-Not Shelf Stable

03I01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. The establishment has implemented controls to ensure data integrity for plan records maintained on computers.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03I Product With Secondary Inhibitors-Not Shelf Stable

03I01	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03I Product with Secondary Inhibitors-Not Shelf Stable

03I02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. The establishment reassessed the	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product. (1) Observe monitoring and verification activities and review, results for a given shipment of product. (2) Review records for a given shipment of product. Make determinations about compliance with regulatory requirements.

03I Product with Secondary Inhibitors-Not Shelf Stable

03I02	HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03J Slaughter

03J01	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directives 5000.1 6150.1 Part 3, Par. III	Review a random sample of HACCP plan features in operation such as: (1) monitoring at CCPs (2) corrective actions taken in response deviations from critical limits, (3) verification Review and correlate records with random observation of establishment activities including the verification that requirements for zero fecal tolerance are met. Take measurements when appropriate. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03J Slaughter

03J01	adulterated product is not distributed. The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; records document slaughter production a shipment of product, product code, product name or other identifier. Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03J Slaughter

03J01	maintained on computers. 417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

03J Slaughter

03J02	The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values. The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. If establishment has substituted an alternative sampling frequency for E. coli, the alternative is an integral part of HACCP verification procedures. The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. The establishment reassessed the	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III	Verify HACCP plan implementation to determine the establishment is following the HACCP plan, establishment personnel perform tasks specified in plan, take corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product. (1) Observe monitoring and verification activities and review, results for a given lot of product. (2) Review records for a given lot of product. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

03J Slaughter

03J02	HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements. Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b) Directive 5000.1 Part 3, Par. III

04A % Yield/Shrink

04A01	X% yield/shrink in all applicable products meets the criteria set forth in the regulations. Actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded/ mislabeled product(s) do not enter into commerce.	Part 319 FSIS Dir. 7310.6 7640.1	Using establishment records and labels, calculate and/or observe product preparation for % yield and/or shrink. To verify compliance, calculate the percentage of cook shrink and/or chill shrink by using the following formula: $\frac{\text{Weight in-Weight out}}{\text{Weight in}} \times 100$ Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04A X% Solution

04A02	Percent added solution in all applicable products meet the criteria set forth in the regulations. Actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/ mislabeled product(s) do not enter into commerce.	319.100- 319.103 381.169 FSIS Dir. 7140.2 7140.3 7640.1 FLD Labeling Policy Book Policy Memos 41B, 42 57A, 59, 66B	Using establishment records and labels, calculate and/or observe product preparation for X% solution. To verify accurate label declaration of the percent added solution, use the following formula: $\frac{\text{Finished wt.-Green wt.}}{\text{Finished weight}} \times 100$ Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04A MSS/MSP/PDBFT/PDPFT/PDCB/PDCP/AMRS

04A03	The establishment meets the criteria set forth in the regulations to ensure that mechanically separated species, mechanically separated poultry, partially defatted beef fatty tissue, partially defatted poultry fatty tissue, partially defatted chopped beef, partially defatted chopped poultry, and meat produced by advanced recovery systems complies with regulatory requirements. Corrective actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled product(s) do not enter commerce.	318.24 319.5 319.6 319.15 (e) 319.29 381.47 (e) FSIS Dir. 7160.1 7160.2 7640.1	Using a combination of establishment records (if applicable) and observation of preparation for the applicable meat and poultry products compare to product standard. To verify compliance, when applicable: - Check product identification, condition, temperature, holding time/storage. - examine bones(for example two intact portions of neck bones or two rib bones) before and after the meat recovery systems, to observe condition and conformation. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04A Batter/Breading

04A04	Batter and/or breading on applicable products meets the criteria set forth in the regulations. Actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded/mislabeled products do not enter into commerce.	319.880 381.166 FLD Policy Memo 89 Procedure/ FSIS Dir. 7640.1	Use establishment records to calculate and/or observe application and final % of batter/breading. To verify compliance, perform batter and breading pick-up tests on one or more subgroups (according to the plant's QC programs) or batches of the product. Use the following formula: $\frac{\text{Breaded Wt.-Green Wt.}}{\text{Breaded weight}} \times 100$ Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04B Labeling

04B01	**Product Standards** A product standard of identity meets the criteria set forth in the regulations. Action is taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure misbranded/mislabeled product(s) does not enter commerce.	Part 319 Part 381, Subpart P FSIS Dir. 7124.1 7640.1 FLD Policy Book	Use establishment records and/or observe product formulation and labeling. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04B Labeling

04B02	**CN/Grade Labeling/Declared Count/Vignette** CN and grade labeled products meet the criteria set forth in the regulations. Declared count and/or vignette on label is accurate. Action is taken when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/mislabeled product(s) do not enter into commerce.	317.8 381.116 FSIS Dir. 6810.1 FSIS Dir. 7010.1 FSIS Dir. 7239.4 7640.1 Rev 1 FLD Labeling Policy Book	Review establishment labels and observe product packaging for declared count vignette, CN, and grade labeled products. Select finished product labels as directed to verify that the label accurately reflects the finished product. Send copies of the labels and requested information to FLD per the FLD sampling audit program. Inspection personnel also can check a sample of production to verify conformance with a QC program. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04B Labeling

	Net Weight		
04B03	Stated net weight/drained weight on package/container meet regulatory requirements. Scales are calibrated and tare weights established. Action is taken by the establishment when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that misbranded/mislabeled product(s) do not enter into commerce.	317.2 (h)(i) 317.18 through 317.22 381.121 (a) thru (e) FSIS Dir. 7240.1 7640.1 Field Manual for In-Plant Meat and Poultry Net Weight Compliance Testing.	Review establishment records and conduct net weight/drained weight, scale calibration, or tare weight checks. To verify scale calibration and tare weight, check scales with available weight and then randomly select the specific number of empty containers, weigh, and calculate the average weight. For QC inspection, follow QC program requirements. To verify net weight/drained weight calculations and statements, inspection personnel can check scales with available weights and then perform net weight/drained weight inspection procedures. For QC inspection follow QC program requirements. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04B Labeling

04B04	**General Labeling** All product is accurately and completely labeled and all ingredients, etc. properly identified in accordance with the criteria set forth in the regulations. Action is taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/mislabeled product(s) do not enter into commerce.	Part 316 Part 317 318.7 Part 319 381.147 FSIS Dir. 6810.2 7131.1 7220.1 7640.1 Labeling Policy Book FLD Policy Memos 16A, 27, 29, 30A, 41B, 51, 93, 102, 103	Review records and/or observe labels, containers, and meat/nonmeat ingredients. Select finished product labels as directed to verify that the label accurately reflects the finished product. Send copies of the labels and requested information to FLD per the FLD sampling audit program. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

04C Finished Product Standards/AQL/Boneless Meat Defect Criteria/Pork Skins/Moisture

04C01	The establishment meets the criteria set forth in the regulations to ensure that all standards other than those with food safety consequences meet regulatory requirements for all applicable products. Food safety requirements are covered in HACCP. Action is taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/ mislabeled product(s) do not enter into commerce.	310.3 318.2 318.5 318.6 381.66 381.76 381.145 FSIS Dir. 6120.1 MPI Bulletins 75-56 78-111 79-42 80-4 FLD Labeling Policy Book	Use establishment records and/or observe plant performance of activities. To verify compliance: - perform pre-chill FPS testing twice per line per shift. -perform post-chill FPS twice per shift - perform giblet AQL testing twice per day -perform carcass AQL test(s) -Perform a lot based boneless meat reinspection or verify operation of plant's QC program by observing reinspection techniques and classification of defects by plant personnel. Observe plant's disposition of a lot of product when a rejection limit is reached. Confirm that all product on hand is reworked and reinspected as identified in plant's program. -perform reinspection on pork skins for popping or verify plants QC program.

04C Finished Product Standards/AQL/Boneless Meat Defect Criteria/Pork Skins/Moisture

04C01		310.3 318.2 318.5 318.6 381.66 381.76 381.145 FSIS Dir. 6120.1 MPI Bulletins 75-56 78-111 79-42 80-4 FLD Labeling Policy Book	-Review plant records/observe plant activities to verify compliance with regulatory requirements relating to moisture adsorption. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

05A Microbiological Sampling

05A01	**E. coli Testing and Criteria** The establishment has written procedures for collecting samples **E. coli** testing. Procedures: identify employee(s) designated to collect samples; address--location(s) of sampling, how randomness is achieved, and handling of samples to ensure sample integrity. Establishment collects samples for **E. coli** testing. Establishment records analytical results on process control chart or table.	310.25(a) or 381.94(a) (Subpart. (1), (2)(I), and (4) FSIS Directive 5000.1 Part 4, Par. II	As appropriate, review procedures and recordkeeping. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).
05A02	The establishment collects samples from the type of livestock or poultry it slaughters in greater numbers; selects carcasses randomly; selects carcasses samples at required location in process, and by procedure specified in the regulations.	§ 310.25(a) or § 381.94(a) Directive 5000.1 Part 4, Par. III	Observe sample collection and review procedures and records. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

05A Microbiological Sampling

05A03	**Salmonella** Applicable product(s), cattle, swine, chicken or turkey; or raw ground product including fresh sausage, may not test positive for Salmonella at a rate that exceeds the applicable national pathogen reduction performance standard.	310.25(b) 318.9 381.94(b) FSIS Directive 5000.1 10,210.1	Collect, process, and mail the sample as directed to determine compliance with the regulatory standard. Based on information provided by the laboratories, make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

05B Economic Sampling

05B01	**Scheduled Sampling** Randomly select as applicable: Cooked sausage 30% fat maximum (total 40% fat+added water) Cooked sausage 10% added water Italian sausage (fat) Fresh pork/beef/breakfast sausage (fat) Smoked pork sausage (fat) Ground beef/hamburger/ground pork Moisture-protein ratio controlled product Dry cured product pH controlled product Corned beef hash Lard PFF controlled product (QC verification only) Fat percentage label claim product (child nutrition label claim) Oleomargarine	318.9 318.19 Part 319 Part 381 Subpart P 381.146 FSIS Dirs. 7110.2 7130.3 7140.2 7330.1 7640.1 10,210.1	Randomly select sample. Process sample and mail to designated laboratory.

05B Economic Sampling

05B02	**Directed Sampling** Collect, process, and mail samples upon request from computer -generated instruction (PFF, bacon, species, potted meat, listeria etc.) or upon instructions from circuit supervisor, district office, or Washington headquarters	381.146 FSIS Dir. 10,210.1 10,520.1	Collect, process, and mail samples upon request from computer-generated instruction (PFF, bacon, species, potted meat, listeria, etc.) or upon instructions from circuit supervisor, district office, or Washington headquarters.

05C Residue

05C01	Samples of poultry and livestock for residue determination, in-plant residue testing (SOS, STOP, CAST, FAST), and diagnostic sampling shall be taken.	310.21 381.9 381.80 381.146 FSIS Dirs. 7355.1 10,210.1 10,220.1	Collect random samples as requested for monitoring and surveillance samples, or submit diagnostic samples as necessary. Inspector generated samples are to be collected as directed or required. Prepare sample and mail to designated laboratory. Perform in-plant residue testing on livestock as required.

06A Export

06A01	A completed application or other request will be furnished to the inspection point with all pertinent information. The product for inspection must meet all foreign requirements, be of current production and in good condition, facilities must be acceptable, plant personnel must be adequately trained to present and stamp product, product presented for sampling must be in acceptable condition whether fresh or frozen, and slaughter dates must be provided upon request. Certificates are completed under FSIS security and copies appropriately distributed by exporter.	322.2 381.105-108 381.111 FSIS Dir. 9000 Series	Review the application or other requests to verify that all pertinent information is included. Check paperwork, certification, marking, and product to ensure that foreign country product specifications are met and product is within allowable production dates. Observe plant personnel assigned to assist in export inspection to determine if adequately trained. Check a lot of product to determine if product is accessible for random selection. Select containers for inspection, adequate marking and labeling. Review foreign countries' requirements for slaughter dates, if required, observe slaughter dates and certification furnished by the applicant. Proofread all documents. Initial minor alterations. Void unusable certificates. Cancel unused space. Sign

06A Export

06A01		322.2 381.105-108 381.111 FSIS Dir. 9000 Series	original and supplemental certificates. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

06B01 Custom Exempt/Retail

06B01	The establishment is conducting custom-exempt/retail-exempt operations in accordance with all applicable regulatory requirements including time/space separation and adequate procedures to assure that product does not bear the mark of inspection. Actions are taken by the establishment when either FSIS or the establishment determines that the standards have not been met. This includes actions to ensure misbranded/mislabeled product(s) do not enter commerce.	303.1 316.16 317.16 320.1 381.10 381.14 381.15 381.175 FSIS Dir. 5930.1	Review applicable records and/or observe plant conditions. To verify compliance, observe area where retail/custom activities are conducted to determine proper separation of facilities and products; review records to verify that hours worked agree with plant's identified schedule. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

06D Facilities and Equipment

06D01	**Facilities and Equipment** Plant facilities (including lighting, ventilation, and plumbing) and equipment meet regulatory requirements and therefore do not pose a public health hazard or result in product contamination. Welfare areas and lockers are clean. Outside premises are clean and orderly. Actions are taken by the establishment when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled product(s) do not enter commerce.	307.2 310.1 381.36 381.76 381 Subpart H FSIS Dirs. 5000.1 5220.1 Rev. 1 7640.1 11,000.2 11,000.4 11,220.2 11,240.5 11,520.4	To verify compliance, review applicable records and/or observe random areas of the establishment facility or equipment, including condition, use, and maintenance. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

06D Facilities and Equipment

06D02	**Inspection Requirements** Inspection and Reprocessing Stations meet the criteria set forth in regulation to ensure they are adequate for the purpose and do not pose a public health hazard. Actions are taken when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled products do not enter into commerce.	308.3 308.8 310.3 381.50(a)-(f) 381.91 FSIS Dirs. 5000.1 5220.1, Rev. 1 7640.1 MPI Bulletin 77-34 78-40 79-68 83-14 83-16	Observe inspection and reprocessing stations condition, use, and maintenance to verify compliance. Verify that linespeeds do not exceed the regulatory requirements. Verify that efficient inspection can be performed on carcasses and parts. Perform at least two presentation tests per shift as per slaughter QC program. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements or NR and (when appropriate) take other action consistent with applicable directive(s).

06D Facilities and Equipment

06D03	**Condemned and Inedible** Condemned and inedible products, salvage of such products, and the facilities where they are handled meet according to regulatory requirements. Actions are taken by the establishment when either FSIS or the establishment determines that the standards have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled product(s) do not enter commerce.	307.2 308.13 310.3 Part 314 318.12 381.53 381.55 381.152 381.193 FSIS Dir. 5000.1 7010.4	Review records and/or observe handling, marking, denaturing, salvaging and/or disposal of condemned and inedible material, and containers. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements or NR and (when appropriate) take other action consistent with applicable directive(s).

06E Sewage

06E01	**Sewage** Sewage handling, treatment and equipment must meet regulatory requirements. Actions are taken by the establishment when either the establishment of FSIS determines that the requirements have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled products do not enter into commerce.	308.3(c) 381.49 381.50 FSIS Dir. 5000.1 11,100.3	Review applicable records and/or observe sewage handling, treatment, or equipment. To verify compliance, check waste facilities and the type of material being handled to see that plant refuse is removed from processing areas, and observe for unacceptable conditions or practices with regard to plant's handling and disposal of waste. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements or NR and (when appropriate) take other action consistent with applicable directive(s).

06F Water

06F01	**Certification** Current water potability certificate supplied by State or local health agency is available. Action is taken by the establishment when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that adulterated product does not enter into commerce.	308.3 381.50(a) FSIS Dir. 5000.1	Check water potability certificate to verify compliance. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

06F Water

06F02	**Requirements** The establishment meet the regulatory the criteria set forth in the regulations. Actions are taken when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled products do not enter into commerce.	308.3(d)(1)(4)(5) 308.8(c) 381.50(a)-(e) 381.66(c) FSIS Dirs. 5000.1 7640.1 MPI Bulletins 77-34 79-68 83-14	Review records and/or observe establishment water use, reuse, chlorination, backflow, and potability. To verify compliance, when applicable: -observe chlorinator or iodinators and determine if functional. Evaluate plant's records of chlorine or iodine testing. -check for cross-connections and identification if nonpotable water is used. -observe plant's water supply system for the following: • Water pressure and sufficiency • Hot water supply • Dead-end pipelines -observe water and steamlines to determine if requirements have been met. Review records of backflow prevention device tests. Make determination about compliance with regulatory requirements.

06F Water

06F02		308.3(d)(1)(4) (5) 308.8(c) 381.50(a)-(e) 381.66(c) FSIS Dirs. 5000.1 7640.1 MPI Bulletins 77-34 79-68 83-14	Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

06G Pest and Rodent Control

06G01	Pest and rodent controls meet all requirements in the regulations to ensure that pests and rodents are not present in the establishment, harborage is not provided, and pesticides and rodenticides are properly used, handled, and stored. Actions are taken by the establishment when either the establishment or FSIS determines that the regulatory requirements have not been met. This includes action to ensure that product contamination does not occur, insanitary conditions do not result, and misbranded/ mislabeled products do not enter into commerce.	308.3(h) 381.59 381.60(a)(b) FSIS Dir. 5000.1 7640.1	Review establishment documentation/ records and/or conduct observation/hands-on of pest and rodent control, harborage, pesticide storage and use. To verify compliance, when applicable: -observe plant's premises for evidence that the pest and rodent control program is effective. -observe the production area or a sample of the area to verify that the pest and rodent control program is effective. -observe the storage of pesticides/rodenticides. Make determination about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

INDEX

FSIS Technical Service Center/District Managers
DM = District Manager DDM = Deputy District Managers ADME = Assistant Deputy Managers for Enforcement

Location and Jurisdiction	Names	Address, Phone & Fax
Omaha, NE	Dr. Paul Thompson, Director Technical Service Center	106 South 15th Street Suite 904 Omaha, NE 68102 Ph. (402)221-7400 Fax (402)221-7438
Alameda, California **States:** California	DM Dr. Murli Prasad DDM DDM Dr. Adel Malak ADME Eleanor Halverstadt	620 Central Ave., Bldg. 2C Alameda, CA 94501 Ph. (510) 377-5014 Fax (510) 377-5081
Salem, Oregon **States:** Alaska, American Somoa, Guam, Hawaii, Idaho, Oregon, Washington	DM Dr. Helmut Blume DDM Pam Ogasawara ADME James Grems	530 Center Street, NE, Rm. 405 Salem, OR 97301 Ph. (503) 399-5831 Fax (503) 399-5636
Boulder, Colorado **States:** Arizona, Colorado, New Mexico, Nevada, Utah	DM Dr. Ronald Jones DDM Dr. Ron Nelson ADME Leonard Ramsey	665 South Broadway, Ste. B Boulder, CO 80303 Ph. (303) 497-5411 Fax (303) 497-7306
Minneapolis, Minnesota **States:** Minnesota, Montana, North Dakota, South Dakota, Wyoming	DM Dr. Nathaniel Clark DDM Walter Olsted ADME Robert Bagley	Butler Square West Ste 989C 100 N. 6th St. Minn. Mn. 55403 (612)370-2400 (612)370-2411
Des Moines, Iowa **States:** Iowa, Nebraska	DM Dennis Greening DDM ADME Martin Hickman	11338 Aurora Ave. Des Moines, IA 50322 Ph. (515) 284-6300 Fax (515) 284-6307
Lawrence, Kansas **States:** Kansas, Missouri ,	DM Dr. William Walker DDM Ronald Kelly ADME Randy Robertson	4920 W. 15th Street Lawrence, KS 66049 Ph. (913) 841-5600 Fax (913) 841-5623

FSIS Technical Service Center/District Managers
DM = District Manager DDM = Deputy District Managers ADME = Assistant Deputy Managers for Enforcement

Location and Jurisdiction	Names	Address, Phone & Fax
Springdale, Arkansas **States:** Arkansas, Louisiana, Oklahoma	DM Dr. Cordell Schilmoeller DDM Dr. Michaelle Fisher ADME Paul Resweber	(temporary location) 216 1/2 East Emma Ave., 2nd Floor Springdale, AR 72764 Ph. (501) 751-8412 Fax (501) 751-9049
Dallas, Texas **States:** Texas	DM Dr. Alan Knox DDM ADME Kenneth Goin	1100 Commerce Street, Rm. 5F41 Dallas, TX 75242 Ph. (214) 767-9116 Fax (214) 767-8230
Madison, Wisconsin **States:** Michigan, Wisconsin	DM Mr. James Blank DDM Dr. Linda Madson ADME Fred Williams	(temporary location) 559 D'Onofrio Drive, Ste. 201 Madison, WI 53719 Ph. (608) 264-5600 Fax (608) 264-5605
Chicago, Illinois **States:** Illinois, Indiana	DM Mr. David Green DDM Dr. Ruth Spargur ADME Louis Leny	(temporary location) 1920 South Highland Ave., Ste 106 Lombard, IL 60148 Ph. (630) 620-7474 Fax (630) 620-7599
Pickerington, Ohio **States:** Kentucky, Ohio, West Virginia	DM Dr. Ellis Jones DDM Jaime Mercado ADME Richard Mackey	155 East Columbus St., Suite 200 Pickerington, OH 43147 Ph. (614) 833-1405 Fax (614) 833-1067
Philadelphia, Pennsylvania **States:** Pennsylvania	DM Mr. Jan Behney DDM Dr. Ram Singh DDM Nabil Makary ADME John Sworen	701 Market St., 2-B South Philadelphia, PA 19106 Ph. (215) 597-8735 Fax (215) 597-4217

FSIS Technical Service Center/District Managers
DM = District Manager DDM = Deputy District Managers ADME = Assistant Deputy Managers for Enforcement

Location and Jurisdiction	Names	Address, Phone & Fax
Albany, New York **States:** Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York Rhode Island, Vermont	DM Mr. George Puchta DDM Shaukat Sved	230 Washington Ave. Albany, NY 12203 Ph. (518) 452-6870 Fax (518) 452-3118
Greenbelt, Maryland **States:** Delaware, D.C. Maryland, Virginia	DM Dr. Perfecto Santiago DDM Dr. M. S. Ibraheim ADME Robert Chubb	(temporary location) 6301 Ivy Lane, Ste. 310 Greenbelt, MD 20770 Ph. (301) 344-2261 Fax (301) 344-2082
Raleigh, North Carolina **States:** North Carolina, South Carolina	DM DDM Dr. Wayne Brooks ADME David Langley	6020 Six Forks Rd. Raleigh, NC 27609 Ph. (919)844-8400 Fax(919)844-8411
Atlanta, Georgia **States:** Florida, Georgia Puerto Rico, Virgin Islands	DM Dr. Lewis Burgman DDM Dr. Milton Benson ADME Donald Crull	100 Alabama St., SW, Ste. 3R90 Bldg. 1924 Atlanta, GA 30303 Ph. (404) 562-5900 Fax (404) 562-5877
Ridgeland, Mississippi **States:** Alabama, Mississippi, Tennessee	DM Dr. Mariano-Loret de Mola DDM James Burt ADME Audie Prewitt	715 S. Pear Orchard Rd. Ste. 101 Ridgeland, Ms 39157 Ph. (601) 965-4312 Fax (601) 965-4993

ISBN 0-16-042771-1